Case Study Descriptions

This report includes five case studies in RRI in or for industry, which were secured using a competition.
Content

1. Executive Summary and Introduction ............................................................................. 6
   1.1. The Method ............................................................................................................. 6
   1.2. The Cases .............................................................................................................. 6
   1.3. The Videos ............................................................................................................. 7
   1.4. Conclusions from the Editor .................................................................................... 8

2. Applied Nanoparticles SL – Spinning off under RRI Principles ....................................... 9
   2.1. Executive Summary ................................................................................................ 9
   2.2. The Company - Applied Nanoparticles SL ............................................................ 10
   2.3. The Product - BioGAS+ by AppNP ........................................................................ 10
       2.3.1. The Concept .................................................................................................. 10
       2.3.2. Technical Description ..................................................................................... 10
       2.3.3. Product Development .................................................................................... 11
       2.3.4. Technology Readiness Level ......................................................................... 12
       2.3.5. Differential advantages .................................................................................. 12
       2.3.6. Patent ............................................................................................................ 13
   2.4. AppNP, BioGAS+ and RRI .................................................................................... 13
       2.4.1. RRI Learning outcomes ................................................................................. 14
       2.4.2. R&I outcomes ................................................................................................ 17
       2.4.3. Societal outcomes ......................................................................................... 20
   2.5. Lessons learned ................................................................................................... 20
   2.6. Appendix 1: AppNPs Code of Conduct .................................................................. 22
   2.7. Appendix 2: Potential Nanoparticles Toxicity ......................................................... 23

3. The development of new rehabilitation devices for use in the community setting – the Rehab Angel ....................................................................................................................... 28
   3.1. Executive Summary .............................................................................................. 28
   3.2. Research and the Product ..................................................................................... 29
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3. Stakeholder collaboration</td>
<td>30</td>
</tr>
<tr>
<td>3.4. Industry Benefits</td>
<td>30</td>
</tr>
<tr>
<td>3.5. Why does this case fall under RRI?</td>
<td>31</td>
</tr>
<tr>
<td>3.6. References</td>
<td>31</td>
</tr>
<tr>
<td>4. Telemedicine for diabetes care – the case of GlucoTel™</td>
<td>32</td>
</tr>
<tr>
<td>4.1. Executive Summary</td>
<td>32</td>
</tr>
<tr>
<td>4.2. Field of Industry or Service</td>
<td>33</td>
</tr>
<tr>
<td>4.2.1. Diabetes as a global societal challenge</td>
<td>33</td>
</tr>
<tr>
<td>4.2.2. The GlucoTel™ system</td>
<td>34</td>
</tr>
<tr>
<td>4.3. Event or Activity</td>
<td>35</td>
</tr>
<tr>
<td>4.3.1. The BodyTel™ ecosystem &amp; stakeholder engagement</td>
<td>35</td>
</tr>
<tr>
<td>4.3.1. Certifications</td>
<td>37</td>
</tr>
<tr>
<td>4.4. Why does this fall under RRI?</td>
<td>38</td>
</tr>
<tr>
<td>4.5. What are the benefits for industry?</td>
<td>39</td>
</tr>
<tr>
<td>5. Organic Solar Cell Development for Clean Sustainable Energy</td>
<td>41</td>
</tr>
<tr>
<td>5.1. Executive Summary</td>
<td>41</td>
</tr>
<tr>
<td>5.2. Field of Industry or Service</td>
<td>42</td>
</tr>
<tr>
<td>5.3. Fabrication Methods</td>
<td>42</td>
</tr>
<tr>
<td>5.3.1. Colloidal mask preparation</td>
<td>43</td>
</tr>
<tr>
<td>5.3.2. Mask modification</td>
<td>44</td>
</tr>
<tr>
<td>5.3.3. Material deposition</td>
<td>44</td>
</tr>
<tr>
<td>5.3.4. Mask lift off</td>
<td>44</td>
</tr>
<tr>
<td>5.3.5. Organic solar cell fabrication</td>
<td>45</td>
</tr>
<tr>
<td>5.4. Light harvesting ability of periodic gold nanowires</td>
<td>45</td>
</tr>
<tr>
<td>5.5. Comparison to the other techniques</td>
<td>45</td>
</tr>
<tr>
<td>5.6. Events or Activity</td>
<td>46</td>
</tr>
<tr>
<td>5.7. Why does the case study fall under RRI?</td>
<td>47</td>
</tr>
</tbody>
</table>
5.8. The industry benefits (Successful application with Ultrathin nanowires - OPV) ..... 48
5.9. References ........................................................................................................... 48
6. “On my own … at work” – a framework and an app ............................................. 50
6.1. Executive Summary.............................................................................................. 50
6.2. Associazione Italiana Persone Down (AIPD)......................................................... 51
  6.2.1. Main AIPD activities focused on the target group (people with DS).............. 51
  6.2.2. Main AIPD activities focused on innovation policy........................................ 51
  6.2.3. Main AIPD activities in the area of job inclusion............................................. 51
  6.2.4. Previous European projects on job inclusion.................................................. 52
  6.2.5. Previous national projects on job inclusion..................................................... 52
6.3. Description of Field of Industry or Service............................................................. 52
6.4. Description of the Product..................................................................................... 53
  6.4.1. Our target group ............................................................................................ 53
  6.4.2. The framework of the “On my own … at work” project for diversity ............. 53
  6.4.3. Why did we design the app? Which needs did we address? ......................... 54
  6.4.4. The app: how is it structured? ...............................................................55
6.5. Product Development, End-User Engagement Activity and Diversity Issues...... 56
  6.5.1. Product development .................................................................................... 56
  6.5.2. Areas of observation ...................................................................................... 56
  6.5.3. A summary of the evaluation of the app by the tutors................................. 57
  6.5.4. Careful design and planning work ............................................................... 57
  6.5.5. Customisation of the app by a disability expert ............................................ 57
  6.5.6. The app is not suitable for everyone ............................................................. 57
  6.5.7. The app: how the trainees used it ............................................................... 57
  6.5.8. Familiarity with apps and technological devices in general........................... 58
  6.5.9. Interest in the app ......................................................................................... 58
  6.5.10. Usefulness ................................................................................................. 58
6.5.11. Distraction and external issues ................................................................. 58
6.5.12. App ‘moments’ ....................................................................................... 58
6.5.13. A supplement of dignity ........................................................................ 59
6.6. Why the “On my own … at work” app is relevant for RRI ............................... 59
   6.6.1. Social justice / inclusion ....................................................................... 59
   6.6.2. Science education .................................................................................. 59
   6.6.3. Open access ........................................................................................... 59
   6.6.4. Rights .................................................................................................... 60
6.7. Potential Benefits ... Not Only for Key Players .............................................. 60
6.8. References .................................................................................................... 61
7. Appendix Case Study Competition .................................................................... 63
   Competition process .......................................................................................... 65
   How to apply ...................................................................................................... 65
   Phase 1 ............................................................................................................... 65
   Phase 2 ............................................................................................................... 66
   Selection criteria ................................................................................................. 66
   About COMPASS .............................................................................................. 67
1. Executive Summary and Introduction

DORIS SCHROEDER

A good case study is a story that invites the reader to share an experience. Case studies are used widely in teaching\(^1\), but are equally useful in other demonstration activities. This report presents five case studies to demonstrate how Responsible Research and Innovation (RRI) can work in industry.

1.1. The Method

To create an additional opportunity for detailed input by stakeholders on RRI, a bottom-up call for case studies relevant to private industry was launched. The case studies were collected using a road-tested schema developed by the Responsible Industry project. The initial call generated four winners, whose case studies form the main part of this report. Given that five prizes were available and that none of the four winners dealt with the area of gender or diversity aspects of RRI, a 2\(^{nd}\) call was launched specifically for RRI and diversity. The 5\(^{th}\) winner completes the set. The launch flyer of the 2\(^{nd}\) phase is attached in Appendix 1. It contains all relevant information about competition criteria and judging.

1.2. The Cases

The five winning cases have an excellent geographical spread across Europe, as they come from Spain, the UK, Germany, Denmark and Italy. The fields covered with the five cases are: nanotechnology (Spain, Denmark), health (Germany, UK) and disability (Italy).

<table>
<thead>
<tr>
<th>Case</th>
<th>Short Description</th>
<th>Main RRI area</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioGAS+ is the first ready to use additive based on safe and sustainable engineered iron nanoparticles directed to the optimization of anaerobic digestion processes, which increases the production of biogas from organic waste.</td>
<td>Sustainable and safe use of new technologies.</td>
<td></td>
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<tr>
<td>The RehabAngel® is an evidence based adjustable incline device which has a flat and 5 degree inverting wedged surface, which gives greater control and safety for patients requiring lower limb exercises.</td>
<td>Broad stakeholder engagement and scientific knowledge sharing with industry.</td>
<td></td>
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<tr>
<td>GlucoTel™ is a sensor for telemedical blood glucose monitoring and diabetes management and is used for automatic, continuous documentation of all blood glucose levels.</td>
<td>Healthy ageing (inclusion) and stakeholder involvement.</td>
<td></td>
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Organic solar is a periodic ultrathin gold nanowire, which provides an alternative nanostructure for indium thin oxide in organic solar cell devices.

"On my own … at work" app supports trainees with Down Syndrome and other intellectual disabilities during their traineeship in the hospitality industry to make them more independent of their tutors.

1.3. The Videos
The COMPASS (710543) team is excited that two case studies are also available as videos!

Please click here for the case videos:
https://innovation-compass.eu/cases/
1.4. Conclusions from the Editor

Whilst the case studies were collected for demonstration purposes, here are two analytical remarks from the editor to conclude.

1. The key RRI action points formulated by the Science with and for Society (SwafS) unit may not fully align with the SwafS RRI definition, which is:

RRI is an inclusive approach to research and innovation (R&I), to ensure that societal actors work together during the whole research and innovation process. It aims to better align both the process and outcomes of R&I, with the values, needs and expectations of European society.

The definition emphasizes the value of inclusion, whilst the key RRI action points only focus on gender issues rather than broader discrimination or exclusion issues.

2. The value of sustainability was considered highly important by case study authors (see Spanish and Danish cases), which also aligns with standard corporate responsibility precepts. Sustainability is not part of the SwafS RRI action points, nor of the RRI definition. This may be detrimental to increasing the interest of industry in RRI.

The value of sustainability should feature more prominently in the SwafS RRI concept to make it attractive to industry.

Doris Schroeder

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2 The case study authors all thanked Julie Cook Lucas and Doris Schroeder for editorial support, and for the diversity case, the same applies to Roswitha Hoffmann.


4 Ibid.

5 See, for instance, the UN Global Compact’s Ten Principles, three of which focus on the environment, https://www.unglobalcompact.org/what-is-gc/mission/principles.

6 The value was included in a SwafS report on RRI indicators, but not taken up more broadly, see: http://ec.europa.eu/research/swafs/pdf/pub_rri/rri_indicators_final_version.pdf
2. Applied Nanoparticles SL – Spinning off under RRI Principles

MARTÍ BUSQUETS-FITÉ, EUDALD CASALS, IGNASI GISPERT, VICTOR PUNTES, JOSEP SALDAÑA

2.1. Executive Summary

Applied Nanoparticles SL (AppNP) is a science-based spin off company founded on 17th October 2013 whose purpose is to research, study and develop nanoparticles and their applications based on Responsible Research and Innovation principles.

We understand RRI as a normative-political orientation that seeks to alter the present sociotechnical order; we are convinced that taking a Responsible Research and Innovation approach to research is the only way of solving the problems we have in the world. From this perspective, a radical reformulation of traditional company values, structures and innovation procedures has been implemented and is explained in the Case Study.

Our company is structured without an explicit CEO, and leadership is taken per project and expertise. Shareholders are actively involved in the day-to-day work and decision making processes of the company. Similarly, employees (scientists) are encouraged to creatively develop and shape their work, and are requested to participate in company governance to help them to enhance their awareness of consequences and their responsibilities. This RRI alignment also affects our legal strategy, and the projects and tools developed for knowledge sharing, generation of debate, and foresight (multidisciplinary education and communication projects, newsletter and twitter account).

AppNP’s core project is the commercial exploitation of a patent named BioGAS+. BioGAS+ is the first ready to use additive based on safe and sustainable engineered iron nanoparticles directed to the optimization of anaerobic digestion processes, which increases the production of biogas from organic waste. BioGAS+ is a disruptive technology because it obtains the highest ever-reported improvement of biogas production, triples the biogas yield with cellulose as feedstock in laboratory conditions, and obtains over a 30% methane ratio increase in real industrial settings, among other additional advantages.

AppNP’s ultimate aspiration when developing BioGAS+ is to transform waste into appealing raw materials in an efficient and sustainable way while contributing to key European policy objectives, such as climate change targets, energy and food security, resource efficiency, improved air quality, the development of bioeconomy and circular economy, bioenergy, and the prevention of contamination.

Experience taken from our daily work in the laboratory suggests that we have to focus on an overarching dimension of RRI: Intelligence (which implies education, study, formation, verification, scepticism, criticism, historical perspective etc.). Responsibility requires complex thinking, wide angle analysis and forecasting of consequences. This is why the ultimate aim of this company, of this project, and of all these efforts, is education in all its forms: proper
education is the only way we know to become more intelligent than we are, and is central to achieving sustainable progress. And we can confirm with optimism that young nanotechnology scientists are eager to adopt a responsible approach to research and innovation, realize that technology is never value neutral, and accept their moral responsibilities; they only need the proper research and innovation environment.

2.2. The Company - Applied Nanoparticles SL

Applied Nanoparticles SL (AppNPs) is a technology-based spin-off company derived from the Universitat Autònoma de Barcelona (UAB), the Institut Català de Recerca i Estudis Avançats (ICREA), and the Catalan Institute of Nanoscience and Nanotechnology (ICN2). The company was founded on October 17th 2013.

The company's purpose is to research, study and develop nanoparticles and their applications. This includes design, production and characterization of nanoparticles, consultancy activities and dissemination, as well as training and education in nanoscience, nanotechnology, and related areas.

2.3. The Product - BioGAS+ by AppNP

AppNP's core project and the main reason behind setting up the company is the commercial exploitation of a patent based on the use of engineered iron oxide nanoparticles for enhanced biogas production, named BioGAS+.

2.3.1. The Concept

BioGAS+ is the first ready to use additive based on safe and sustainable engineered iron nanoparticles directed to the optimization of anaerobic digestion processes which increases the production of biogas (a mixture of different gases produced by the breakdown of organic matter in the absence of oxygen, mainly CO₂ and CH₄). Thus, the process that converts organic waste into raw matter for energy production is optimized by simply adding a small dose of iron (Fe) based nanoparticles (NPs) to either a large waste treatment reactor, a septic tank, or a homemade biodigester.

2.3.2. Technical Description

It is known that the addition of Fe ions to an anaerobic bacterial reactor can increase methane production, however introducing such ions can give rise to toxicity and excess reactivity. These problems are solved with BioGAS+ iron based nanoparticles: NPs can be designed to corrode and dissolve in a controlled manner, thereby providing a Fe optimized dosing source because of their denseness, chemical composition, crystal structure, nanometric size, and high reactivity. In conditions of anaerobic digestion small doses of mixed iron oxide NPs serve as a catalyst that stimulates bacteria metabolism and accelerates the production of biogas.
2.3.3. Product Development

Work on the use of iron oxide NPs to enhance biogas production started in 2008 with a project called NANOCLEAN, funded by the Spanish Environmental Ministry. The initial objective was the study of the potential toxic effects of different common NPs in bacterial consortia intended for waste water treatment plants (WWTPs). If NPs became common in consumer products, they will inevitably end up in WWTPs, our environmental gate keepers. To our surprise, instead of proving toxic, some iron oxide nanoparticles were beneficial. After repeating the experiments and performing the corresponding controls, the phenomenon was consistently reproduced, and so we decided to start filing a patent to protect it. After that, the institutions involved in the project – the patent owners - carried out a series of unfruitful technology transfer promotion activities in specialized forums and conferences. Technology brokers, mainly, showed some interest in our product at international and local science-business fairs, but this did not develop far as the technology was considered too immature, and not yet of interest to (nanotechnology) business angels. Indeed, today, regarding the Technology Readiness Levels (TRLs, 1 to 9, from the Eurek! to placement in the market),7 inventors hurry to protect their discoveries at levels 2-3 but they are usually not minimally commercializable until TRL 6/7. Therefore, we decided to overcome what we called “TRL gap” by looking for alternative funding, namely, altruist funding, industrial partners, EU / national support programs and activity diversification:

1. Altruist Funding: In 2011 we obtained funding from the Bill & Melinda Gates Foundation Grand Challenges Explorations Grants (proposal OPP1044410). In 2012 we presented our project to the Fundación Repsol8 Entrepreneurs Fund9 and were selected for a one year pre-incubation award (as our technology was immature). In 2013 we obtained the Ibero-American Secretariat General Innovation and Entrepreneurship Award.10 In 2014 we submitted a new proposal to the Fundación Repsol and were awarded their incubation prize, which consisted of mentoring, education in entrepreneurship, and basic funding for two years (finishing in September 2016).

2. Industrial Partners: We have searched for alliances with industrial partners with the strategic objective of sharing part of our know-how and exclusive rights to BioGAS+ in exchange for their know-how and resources. We have seen that Industrial Partners are conscious of the time needed for getting the right, safe, sustainable products. On the other hand, since BioGAS+ reached TRL 6/7 we have received several proposals from venture capitalists / business angels that we have

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7 TRL is a measurement system of the maturity level of particular technologies. This measurement system provides a common understanding of technology status and addresses the entire innovation chain. [https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf)

8 Fundación Repsol is one of the means by which Repsol fulfills its commitment to social responsibility, acting as a channel for the company’s social and cultural work. Its objective is to contribute to social wellbeing, improve people’s quality of life, and achieve greater social, educational, environmental and cultural development [www.fundacionrepsol.com/en/the-foundation](http://www.fundacionrepsol.com/en/the-foundation)

9 The Fundación Repsol Entrepreneurs Fund is aimed at entrepreneurs with innovative technological projects in the field of energy and energy efficiency who have set up or intend to set up a company. The Fund’s objective is to support them in taking their solutions to the market as quickly as possible. [www.fondoemprendedores.fundacionrepsol.com/en/entrepreneurs-fund](http://www.fondoemprendedores.fundacionrepsol.com/en/entrepreneurs-fund)

10 The Ibero-American Secretariat General (SEGIB) is an international support organisation of the Ibero-American Summit of Heads of State and Government, which implements its mandates and drives Ibero-American Cooperation in the areas of education, social cohesion and culture [http://segib.org/en/who-we-are/](http://segib.org/en/who-we-are/)
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 710543

rejected as they impose requirements for unrealistically fast timescales to bring products to market, or transform the project into some financial derivative in order to raise funds.

3. EU / national Support Programs: We have obtained funding from EU cooperation programs (H2020), and support from the SMEs Instrument (1st stage).


2.3.4. Technology Readiness Level
As explained, BioGAS+ is the result of intensive research that started in 2008. Since then we have travelled the long road from laboratory to market. The first tests were carried out in laboratory settings with discontinuous digesters. Subsequently these results were confirmed with different feedstock (urban waste, slaughterhouse waste, manure, and weed) directly provided by different end-users (companies) and tested in continuous pilot laboratory digesters.

At present, BioGAS+ is being tested at the industrial premises of a global sewage sludge biogas plant operator (starting with test digesters of 1.5m³ -TRL7- and then in digesters of 500m³ or above -TRL8). A specific plan for testing BioGAS+ in real industrial digesters for other selected sectors and feedstock (agricultural residues, farm waste, food and beverage, and organic fraction of municipal solid waste) has also been set up, and will be implemented in 2017. BioGAS+ has already been produced in (pre) bulk quantities which prove the industrial scalability of our product (60 kg in 500 L reactors). During 2017 we will be producing hundreds of kgs and afterwards tonnes (t) of BioGAS+. For these reasons, we consider that TRL9 will be achieved in 2017.

2.3.5. Differential advantages
Increase biogas and biomethane production. BioGAS+ is a disruptive technology because it obtains the highest ever-reported improvement of biogas production: triples the biogas yield with cellulose as feedstock in laboratory conditions -DIN-38414-11 and obtains over a 30% methane ratio increase in real industrial settings, with real feedstock and with optimal concentrations below the 1% (with respect to the Volatile Solids). Such a methane production increase is far above any known technology aimed at increasing biogas production: many existing technologies approach this problem (i.e. pre-treatment of the biomass, thermalization of the waste, combination of feedstock and inoculums) but only obtain modest production increases. Moreover, many tend to be costly to implement since they usually require structural changes in the biogas production process. The unprecedented methane ratio increase is the most appealing advantage of BioGAS+, but it also offers additional differential advantages, including:

- Improved biomass to biomethane conversion efficiency.

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Better biogas composition (higher methane share).
Higher waste degradation. An improvement of anaerobic digestion of biomass will lead to a less bioactive end-of-waste digestate, which is more appealing for composting and re-use.
Acceleration of the digestion process. Reduction in retention / residential time\(^{12}\) and in the digestate fraction.
Enrichment of the residual material (digestate) with iron ions to obtain by-products with increased economic value such as high quality fertilizers.
Additive (it does not require any change in the biogas plant industrial process).
As proved suitable for "difficult to digest" feedstock it enlarge available biomass feedstock previously discarded or recalcitrant organic matter.
Reduced AD plant energy consumption.
Minimization of undesirable side effects in biogas plants such as the odours associated with HS and NH3, thus reducing the cost of associated conditioning measures.

2.3.6. Patent
The Private Foundation Catalan Institute of Nanoscience and Nanotechnologies (ICN2), the Catalan Institute for Research and Advanced Studies (ICREA), and the Autonomous University of Barcelona (UAB) are the owners of "a method for increasing the production of biogas in anaerobic digestion processes of biodegradable material by adding nanoparticles iron oxide". The Patent owners and Applied Nanoparticles SL have signed an Exclusive Licencing Agreement dated 21/07/2015. This method is protected in Europe by patent application 12707361.7.1352 Ref. P1923EP01/EP2683662 and in the USA under Patent US 9,416,373 B2 dated August 16\(^{th}\), 2016 BIOGAS PRODUCTION

2.4. AppNP, BioGAS+ and RRI
We understand RRI as a normative-political orientation that seeks to alter the present sociotechnical order. From this perspective a radical reformulation of traditional company values, structures and procedures (including decision making and innovation procedures) has to take place. This is what we are trying to achieve at AppNPs with BioGAS+. Otherwise, we

\(^{12}\) Reducing the residential time of the feedstock inside the digester allows rationalization of a biogas plant’s investment strategies (plant dimensions / new plants).
will be facing what can be named “responsible-washing” (following the well-known “green-washing” \(^\text{13}\) in the Corporate Social Responsibility framework).

In this Section we present our work on RRI. In doing so, we follow the RRI concept as developed by the RRI Tools Project\(^\text{14}\) that specifies outcomes and process requirements.\(^\text{15}\) RRI outcomes can be separated into learning outcomes (engaged publics, responsible actors, responsible institutions), research and innovation outcomes (ethically acceptable, sustainable, socially desirable), and societal outcomes (solutions to societal challenges - Grand Challenges). In order to achieve these outcomes, the RRI process has to meet certain process requirements that have been divided into four clusters, namely, diversity and inclusion, anticipation and reflection, openness and transparency, responsiveness and adaptive change. Following this framework, we present a set of AppNPs outcomes linked to the corresponding process requirements.

### 2.4.1. RRI Learning outcomes

**Shareholding and decision-making process (Diversity & Inclusion)**

The company is made up of 13 shareholders, with no single shareholder having more than 10% of shares. Among them are researchers in Nanoscience and Nanotechnology or Environmental Science (inventors of Biogas+) and representatives of other disciplines; law, marketing, e-communication and graphic design. 10 out of the 13 shareholders are or have been directly or indirectly involved in the day to day work of the company.

This structure makes the company diverse, and robust against modifications and unexpected transformation of the initial aims, as a democratic majority of shareholders is required for fundamental decision making. The company is structured without an explicit CEO. The implementation of the resolutions adopted is delegated to the most suitable and most available person, in a knowledge-based functional (expertise and facts driven) system where efficiency is prioritized over efficacy, and efficacy is not at all neglected. In general, decisions and strategies are agreed between the legal representative, the scientific director, workers and active shareholders.

**Retaining talented employees (Diversity & Inclusion / Responsiveness & adaptive change)**

In a spin-off company, human resources are critical: with no financial strength or infrastructures, knowledge and human resources are our only competitive tools. Therefore, highly motivated and skilled employees are needed, but one may not be able to retain them in small companies for a long period (they may pursue their academic and investigation career, or you may not be able to compete financially). In our case, the way to retain human capital

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\(^{13}\) Spends more time and money claiming to be “green” (e.g. in advertising) than implementing business practices that minimize environmental impact.

\(^{14}\) Funded under the Framework Programme FP7 (2007 – 2013), RRI Tools has been set up to develop a set of digital resources to advocate, train, disseminate and implement RRI under Horizon 2020. https://www.ri-tools.eu/

\(^{15}\) “Responsible Research and Innovation is a dynamic, iterative process by which all stakeholders involved in the R&I practice become mutually responsive and share responsibility for both the outcomes and the processes involved”. https://www.ri-tools.eu/documents/10184/107098/RRITools_D1.1-RRIPolicyBrief.pdf/c246dc97-802f-4fe7-a230-2501330ba29b
has been a combination of two concepts, namely: “a company in the making” and “a company with purpose”.

When talking of “a company in the making” we refer to the possibility of directly influencing the direction the company is heading based on the decision taking procedure explained above (collaborative decision making procedure and personal responsibility for follow up actions). This gives plenty of room for personal development possibilities, depending on the level of involvement that each person is able and willing to provide. The company thus serves as a platform for project development and opportunities generation.

By “a company with purpose” we refer to our vision as a company and how we want to achieve it. We want to become a reference for nanotechnology applications in these early days of nanotechnology development, driven by principles of Responsible Research and Innovation in order to generate wealth responsibly, minimize deleterious side effects, and pay special care to sustainability. All of our activities, resources and funds are directed to this objective. The vision is present in the day-to-day laboratory work; principles and action go together and can be directly experienced.

Innovating responsibly as the cornerstone of the legal strategy (Responsiveness & adaptive change)

It is well known that there are no specific regulations for nanotechnologies or nanomaterials at EU level. Instead, the manufacture, use and disposal of nanomaterials are covered, at least in principle, by a complex set of existing regulatory regimes. As the current regulatory regime applicable to Nanotechnology and Nanomaterials (N&N) was not designed for nanomaterials, it is (in some ways) inadequate. The consequence of this inadequacy to private economic operators regarding their legal obligations (compliance) is legal uncertainty. Consequently, where explicit nano-regulations do not exist, and the economic operator is faced with open legal concepts, the most sensible course of action is to focus on risk avoidance, which implies low impact production techniques - green chemistry - as well as the way in which nanomaterials are embedded into products - safe by design / design for safety. In other words, in the current legal framework and social context, companies need to develop safe and sustainable nanomaterials, and applying RRI principles is the best way we found to achieve it.

16 Those inadequacies are essentially: knowledge, regulatory design and information gaps. They are filled by 3 different regulatory methods: a) by entering explicit “nano” references to existing regulatory regimes for chemicals (Regulation (EC) No. 987/2008 amending REACH as regards Annexes IV and V, OJ L268/14 by which Carbon and Graphite were removed from exemption list Annex IV; b) by proposing regulatory reviews on nanomaterials (such as the one under consideration regarding REACH); and by c) promoting anticipatory legal governance to private operators, based on the use of soft law mechanisms.
Newsletter and twitter account (Anticipation & reflection / Openness & transparency)

Whilst acknowledging that the continuous and consistent involvement of society in the research and innovation process is one key aspect of RRI, it has to be recognised that from the perspective of a start-up, this task has to be approached with caution and respect. It is not only economic constraints, but the inherent difficulty in setting up public engagement practices (methods of participation, purposes, evaluation criteria, etc.) that make this a challenge. For these reasons we have chosen to involve stakeholders and society at large by promoting a permanent dialogue through our twitter account (https://twitter.com/biogasplu), and our open source monthly newsletter https://www.biogasplus.info/biogas-newsletter/. These tools go well beyond current information services, as our aim is to filter, curate and contextualize information in the fields of biogas and nanotechnology.17

Our final aim is to generate debate and foresight (inside and outside our company) on fundamental topics. From an RRI perspective, one such topic is the ethical debate around biogas18 which, as we will see when discussing our Code of Conduct, below, has influenced our approach to market (and our business plan) in a fundamental way.

Researchers’ Responsibility Awareness (Anticipation & reflection)

Following Schuurbiers19 we consider that researchers have a moral responsibility to pay attention to and critically reflect on the wider socio-ethical context of their work, specifically:

i. The “value-based socio-ethical premises” of research;
ii. Epistemological and ontological assumptions;
iii. Methodological norms of scientific culture; and
iv. The socio-ethical consequences of research.

As we are working in and from the laboratory, we are especially interested in the “midstream”20 phase as an opportunity for addressing social and ethical concerns.

17 BioGAS+ newsletter and twitter concept: Today we have an unlimited amount of content; what is valuable is filtering and curating; making sense of the information. BioGAS+ Newsletter does this work by filtering and curating in the field of nanotechnology, biogas and responsible innovation. There is a unique process of on-going monitoring, selection and presentation of information from the original source, with correspondence, and in some cases even collaboration with, the authors of the research. The capsules (news) resulting from the monitoring and filtering of information seek to provide extra value: the context. This is achieved by the information itself and also by promoting debate / controversy and / or a contrast of opposing paradigms in the same capsule (by means of the context and follow up). The compilation of the capsules over time has become an online database with its own search tools and labelling information, which is updated and contextualized in book format (electronic and paper) with a unique signature graphic.

18 Just a few examples of different news published and contextualized in our newsletter regarding ethical concerns: May 2015. “If global food waste were a country, it would rank third in terms of greenhouse emissions”; April 2015. Restricted Expansion of Food for Fuel: Waste-Biogas, Next Generation Biofuel; March 2015. Waste-biogas or crop-biogas?; January 2015. “We need to move from the food versus fuel debate to a food and fuel debate”; December 2014. Biogas and Food Security Debate; December 2014. UK: Milk in biodigesters


20 ‘Midstream’ denotes the phase of the research and development before scientific results are translated into products or services, but after authorization and funding decisions have been taken. Fisher, E., Mahajan, R.L., Mitcham, C. “Midstream Modulation of Technology: Governance From Within”. Bulletin of Science, Technology & Society. Vol. 26, No. 6. December 2006, 485-496.
Bearing in mind our economic and human constraints we have structured the midstream modulation around periodical informal review meetings. In those meetings we analyse the technology and business aspects of our business and a review of the most interesting information published by our newsletter (and feedback received) is discussed. Overall, a wide range of topics are reviewed (environment, health and safety, sustainability, patenting, long-term research and business strategies, ethical issues and the responsibility of scientists to communicate with society). Our experience points to a “two way embedding” between social and natural scientists. All members of the organization, whatever his/her background, become involved and aware of the social and institutional constraints in which we have to operate (balancing scientific and commercial interests, coping with the demands of clients, the complexities of research practices etc).

**Responsible Nanosafety Experts (Anticipation & reflection / Responsiveness & adaptive change)**

Our vision is that every (nano)scientist should become a “responsible (nano)safety expert”. This is, all workers involved in our project have basic skills on nanosafety and nanosustainability. This concept came to us from the “expert patient” definition, and it is putting in practice the idea that all responsible citizens should know first aid techniques. We are currently developing (within the framework of a collaborative H2020 project) a training course for nano-doctoral students that will combine “hands on RRI in the lab” with “tutorials on broader RRI concepts”. The final objective is that the doctoral students re-analyse their doctoral thesis in the light of the learned RRI concepts and practices.

**Multidisciplinary education and communication projects (Openness & transparency)**

We are convinced that for a smooth introduction of nanotechnology in society, openness and education are fundamental factors. For this reason, AppNPs and / or our shareholders are very active in undertaking projects that bring Nanoscience and Nanotechnology (N&N) to society. Among others, we can mention the information service Nanowiki, NanoColoringBook, GoldLight Quantum Jewellery, production and / or sponsoring of general and technical audience books related to N&N, and collaboration with the Barcelona University (UB) Nanodivulga Project, among other.

### 2.4.2. R&I outcomes

**Ethical acceptability (Diversity & Inclusion / Openness & transparency)**

Within a company, its core values (or constitutional values) are expressed within its Code of Conduct (CoC). The normative targets set in the CoC “have been democratically agreed and provide the legitimate basis for defining the type of impacts that research and innovation

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21 Nanowiki information service has been considered among the 10 most influential nanotechnology accounts by Hope Reese from TechRepublic: [http://www.techrepublic.com/article/nanotech-10-twitter-accounts-to-follow-to-keep-up-to-date/](http://www.techrepublic.com/article/nanotech-10-twitter-accounts-to-follow-to-keep-up-to-date/)


23 [http://www.theguardian.com/what-is-nano/precious-particles](http://www.theguardian.com/what-is-nano/precious-particles); [https://www.facebook.com/goldlightjewels](https://www.facebook.com/goldlightjewels)/

24 [https://archive.org/search.php?query=creator%3A%22v%C3%AD%C2%ADctor%22puntes%22](https://archive.org/search.php?query=creator%3A%22v%C3%AD%C2%ADctor%22puntes%22)

25 [http://www.ub.edu/laubdivulga/nanodivulga/](http://www.ub.edu/laubdivulga/nanodivulga/). A set of activities aimed at bringing the world of nanotechnology to the public.

should pursue” 27 within AppNPs. At AppNPs those “anchor points” 28 have been discussed among shareholders and workers. We believe that this exercise helps to understand the higher values that have to be taken into consideration when laboratory decisions on safety and sustainability are taken on a daily basis.

The values that we have agreed upon for our CoC are those that we all recognize as universal (human dignity, solidarity, sustainability, social justice, transparency and democratic participation) and they imply that all actions and decisions should be directed to seek social, economic and environmental sustainability, and not to seek individual or only economic benefits. In this sense, our company understands that these values should also substantiate economic relations and, in this regard, shares the principles of the Economy for the Common Good (ECG). 29

We understand that the CoC has to be a “living framework” from which concrete ethical discussions and lines of action have to be derived. In this sense, and from an RRI perspective, one such topic is the ethical debates around biogas that are influencing our approach to market (and our business plan) in fundamental ways. For example, the German market represents approximately 50% of the total biogas market in the EU. From it, 48% (by weight) or 77% (by energy output) of biogas is produced with “crop feedstock”. This reality confronts us with the ethical “food vs. fuel” debate (bioenergy production may compete, directly or indirectly, with food production, and as a consequence food security may be adversely affected). Based on ethical grounds we have decided to develop products for anaerobic digestion plants using waste as feedstock. Having in mind the market figures given, there is no need to expand further on the far reaching consequences of our decision.

Safe and Sustainable outcomes (Anticipation & reflection)

Our previous experience in the fields of nanosafety & nanosustainability 30 - mainly through collaborative projects under EU FP6 and FP7 and the participation in the Centre for NanoBioSafety and Sustainability (CNBSS 31 ) - have made us familiar with how to follow and implement concepts and procedures such as “safety by design”, “green chemistry” and Life Cycle Assessment (LCA). We provide our product BioGAS+ to other research laboratories under the H2020 program to openly study the potential (eco)toxicity of our product. Regarding Safety, we follow broader Nanosafety Guidance and Frameworks published by some European institutions focused on nanosafety, as NanoRiskCat – A Conceptual Decision Support Tool for Nanomaterials (from the Environmental Protection Agency of the Danish Ministry of the Environment) 32, and Working Safely with Nanomaterials in Research &

28 Ibid.
29 https://www.ecogood.org/eng
30 https://www.biogasplus.info/2017/01/25/potential-nanoparticles-toxicity/
31 http://www.cnbss.eu/
32 NanoRiskCat – A Conceptual Decision Support Tool for Nanomaterials (from the Environmental Protection Agency of the Danish Ministry of the Environment). We follow it as our benchmark framework on Risk Assessment of Nanomaterials. It provides clear and detailed guidance on mapping and assessing risk that yields
Regarding **Sustainability**, AppNP is committed to work in the greenest and most environmentally friendly conditions possible, by following the 12 Principles of Green Chemistry developed by Paul Anastas and John Warner in 1998; a list of requirements that an ideal "green" or environmentally friendly chemical, process or product would follow or accomplish.\(^{34}\)

We are confident that the production process of our main product, based on magnetite (Fe\(_3\)O\(_4\)) nanoparticles follows all of the aforementioned principles to some degree, starting with the low inherent hazard of the product itself. There is plenty of literature about the innocuous or very low toxic nature of magnetite nanoparticles,\(^{35}\) iron being a life-essential *oligoelement*, and iron oxides, even in the nanometric form, are natural abundant materials.\(^{36}\) Our raw materials cannot be considered scarce or non-renewable feedstock. Moreover, in our production process the nanoparticles are synthesized *in situ* in aqueous media at room temperature and are always processed as a colloid, never as a dry powder, thus avoiding airborne exposure. Being carried out at room temperature, the production process has a very low energetic demand (except for the generation of the required stirring power). The washing waters of the NP production are recovered and directly used as base for further synthesis. Regarding the application, the size and dose of the nanoparticles are purposely designed to completely dissolve during the tens of days of a standard anaerobic digestion retention times.

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\(^{33}\) *Working Safely with Nanomaterials in Research & Development* (developed by The UK NanoSafety Partnership Group and the Institution of Occupational Safety and Health (IOSH) within the Health and Safety Executive (HSE) of the UK Government). This is very general on dealing with all sorts of nanomaterials in a safe way, and we consider that some amendments should be made to include more nanoparticles focused to completely suit our circumstances, but we follow it for its concise and useful guidance on some areas, especially on Engineered Exposure Control Measures, Personal Protection Equipment, Disposal of Nanomaterials and Labelling and Signs.


\(^{36}\) [http://www.lulu.com/shop/v%C3%ADctor-puntes-and-josep-salda%C3%B1a-cavall%C3%A9/nanoparticles-before-nanotechnology/ebook/product-206356604.html](http://www.lulu.com/shop/v%C3%ADctor-puntes-and-josep-salda%C3%B1a-cavall%C3%A9/nanoparticles-before-nanotechnology/ebook/product-206356604.html)
2.4.3. Societal outcomes

Solution to societal challenges – Grand Challenges - (Responsiveness & adaptive change)

AppNP’s final aspiration when developing BioGAS+ is to transform waste into appealing raw materials in an efficient and sustainable way while contributing to key European policies, such as climate change targets, energy and food security, resource efficiency, improved air quality, the bioeconomy and circular economy, bioenergy, prevention of contamination.

Specifically, the urgency in tackling climate change and promoting renewable sources of energy has been universally agreed as one of the Grand Challenges of our time. We have also seen EU policy and regulatory alignment with this global challenge. But as per today, biogas production represents a small share of the total renewable energy sector (10.9 Mtoe\(^3\) of biogas in 2010 and an estimated production of 39.5 Mtoe in 2020, i.e. approximately 10% of EU natural gas consumption). The main cause of this underuse is the difficult optimization of the complex processes occurring inside anaerobic digesters and, as a consequence, the low conversion rates of biomass (waste) to energy (gas/methane), leading to economic inefficiency. As we have seen, BioGAS+ can transform actual biogas production into a profitable business, thus helping to combat climate change and promote renewable energy systems.

2.5. Lessons learned

In their foundational article “Developing a framework for responsible innovation”, Owen and colleagues\(^3\) present four dimensions of responsible innovation, namely; Anticipation, Reflexivity, Inclusion and Responsiveness. Experience taken from our daily work in the laboratory suggests that we have to add a fifth dimension, or perhaps an overarching sine qua non: Intelligence (which implies education, study, formation, verification, scepticism, criticism, historical perspective etc.).

In an over simplified manner, those who contaminate the river or abuse the workers do not do so because they enjoy river death or making others suffer. When the businessman says that he cannot compete without pressurising workers, polluting the environment and cheating on consumers (see the recent “clean diesel”\(^3\) case) this is due to a lack of intellectual capacities or low knowledge and reasoning capabilities. As Winston Churchill said, “gentlemen, we have run out of money, now we have to think”. Now we are not running out of money, we are running out of a clean planet. Therefore, we cannot afford foolishness, it is too expensive. Responsibility requires complex thinking, wide angle analysis and forecasting of consequences. This is increasingly the case in a world becoming more and more sophisticated thanks to technological development. Now that we need to start to develop more efficient technologies, and truly understand sustainability, we witness with dismay the

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\(^3\) Million Tonnes of Oil Equivalent.
\(^3\) https://en.wikipedia.org/wiki/Volkswagen_emissions_scandal
new illiteracy that is rising, where signs of post-enlightenment are starting to be visible, probably as a consequence of the increased complexity. This is why the final aim of this company, of this project, and of all these efforts, is education in all its forms: proper education is the only way we know to become more intelligent than we are, and the only way towards sustainable progress.

From our experience (through conferences, EU nanosafety cluster, twitter account and so on) we have seen that mature and established professionals often, probably influenced for an interest in the actual status quo, think that they are already “responsible”, and look at this movement with sympathy and condescendence, while young nanotechnology scientists, who have not yet established professional lives are more eager to adopt a responsible approach and realize that technology is never value neutral, but always value-laden. They accept their moral responsibility (to critically reflect on the wider socio-ethical context of their work), and are thus ready to understand RRI as a political tool. They only need the proper innovation environment.

(* All pictures have been taken by Dr Victor Puntes using a Transmission Electron Microscopy – TEM)

Please also see the accompanying video for this case study:

https://innovation-compass.eu/cases/

2.6. Appendix 1: AppNPs Code of Conduct

Our Code of Conduct reads as follows:

1.- OBJECT

The object of this Code of Conduct is to define the principles and standards of ethical conduct that should govern the actions of the related persons in the exercise of their professional activities in their relationship with the Company.

2.- SCOPE

The Code shall apply to Applied Nanoparticle SL and the following people:

i) Managers, directors and any person employed by Applied Nanoparticles SL,
ii) Any natural or legal person hired by Applied Nanoparticles SL for the provision of services and for the Company and
iii) Any other natural or legal person determined by the directors.

3.- ETHICAL PRINCIPLES

The values that should govern the actions of all persons subject to it are those that we all recognize as universal: human dignity, solidarity, sustainability, social justice, transparency and democratic participation (in line with the guidelines established at the European level by tart. 3 ap. 1, 2, and 3 of the Maastricht Treaty and the Charter of Fundamental Rights of the European Union. OJ C83 of 30.03.2010).

In all areas of our company these universal values imply that all actions and decisions should be directed to seek social, economic and environmental sustainability and not to seek individual or only economic benefits. In this sense, our company understands that the values embodied should also substantiate economic relations and, in this regard, shares the principles of the Economy for the Common Good and will carry out actions for internal application, and knowledge dissemination.

These principles and objectives create standards of ethical behaviour listed below:

4.- ETHICAL STANDARDS OF CONDUCT

RELATIONSHIP WITH WORKERS

4.1.- HEALTH AND SAFETY IN THE WORKPLACE. Aware of the limitations of applicable law, AppNPs considers that it has to go beyond compliance with regulations on Safety and Health at Work. Therefore internally we apply good practices stemming from the nontechnology academic laboratories and environments of the nanosafety cluster (www.nanosafetycluster.eu). We are also educating our workers on basics of NP toxicity and safety from a broad and fundamental point of view to transform our workers into nanosafety experts.

4.2.- WORKERS RIGHTS & OBLIGATIONS

We seek the active participation of workers in all aspects of the organization and recognize their contribution to the increased value of the company by applying incentives and bonuses to share with those responsible for that increased value. Employees have authorized personal use of the resources of AppNPs, but this should not be excessive, nor for personal gain or illegal purposes and should not be abusive in any other way. Employees should not use their position to obtain direct or indirect personal benefit.

We promote the smooth development of work, following general visions and interests, rather than being restricted to the strictly planned and commanded agenda (which would be a poor method for progress).

We advocate equal opportunities; we maintain an environment free of harassment and other primitive behaviour, and we ensure privacy of personal data.

4.3.- RELATIONSHIP WITH THE PRODUCTS OF INNOVATION

We develop all our products under the principles of Responsible Innovation, both from the point of view of the product (it has to be useful, sustainable and safe) and process (it has to be collaborative and inclusive). As a result: Innovation is addressed to social benefit; ethical considerations of impacts at social and environmental levels are considered; the security of the product is studied through its full life cycle, from its production to its disposal or reuse, addressing the health and safety of workers and consumers.
4.4.- RELATIONSHIP WITH INTEREST GROUPS

We need collaboration with suppliers and customers throughout the supply and value chain. In this context, transparency and disclosure of information is mandatory to open a sincere 2-way dialogue with all stakeholders and society. Our priority will be to interact with customers and suppliers who share the values, principles and standards reflected in the Code of Conduct. We understand a market economy based on cooperation between operators reflecting the finding that scientific innovation is a historic cooperation of countless thinkers and researchers. We also understand that only people working in and / or for the company should share in the profits it generates. This is in line with prioritizing productive economy over financial economy. We do not contemplate the possibility of sharing the profits of the enterprise among people who have not added value to the organization. Any investment in the Company will be addressed (internally) to strengthen the capacities of Responsible Innovation and (in the external environment) to those activities oriented to the common good and to improve the quality of life. We are working exclusively with ethical banking and / or cooperatives. Our experience is that in these institutions we get a better service at a better price.

4.5.- RELATIONSHIP WTH SOCIETY

In our relation with society we are committed to sustainable development. We understand sustainable development in its three dimensions: environmental, economic and social. In this sense: i) the product of our innovation should be aligned with the 2030 Agenda for Sustainable Development of the UN (Resolution adopted by the General Assemblies of September 25, 2015. A / 70 / L1), and we are committed to integrating the ten principles of the Covenant UN World in our business strategy and operations by implementing its Management Model, and ii) the product of our innovation will have as design requirements: environmental protection, collective security and public health.

2.7. Appendix 2: Potential Nanoparticles Toxicity

Today, the majority of innovation in nanotechnology is restricted to spin-offs generated in the academic environment where funding agencies set research efforts towards common goods, in medicine, energy and environment. From the societal point of view, and for similar reasons (small companies cannot financially support worldwide patents), patents are only presented in rich countries where benefits are more secured, allowing its free implementation in the rest of the world. Therefore, in these cases, the most critical point regarding responsible development is safety, and safety comprises human and environmental safety. Therefore, the question we need all to pose is: does the nanoform of a substance entail an increased risk? This question is fundamental to us. The potential negative impact of nanotechnology in health and the environment has worried society, and even if this is often overlooked by scientists, technologies need to get introduced into social environments and therefore the applications that develop are shaped by a mix of social and technological forces. If society embraces and finds uses for a technology, then it survives. Otherwise, not matter how good the technology is, it will die. Thus, effective communication is mandatory, which should include, in addition to state-of-the-art performance, safety studies, and a nanosafety-by-design approach contributing to full life cycle assessments and viability studies. Because of this, we take the advantage to describe our position regarding potential nanoparticles risk in the frame of our work.

The surprising properties of NPs are fundamentally due to their high surface to volume ratio, finite size effects, collective behaviour and interaction with light of any wavelength (for hyperthermia, diagnosis and imaging purposes) This results in a broad spectrum of chemical, physical, catalyst, optical and magnetic behaviours which can be sized for many uses. Interestingly, their exuberance of degenerated states at the macromolecular level allows their use as versatile molecular sensors and actuators, as much as it makes them complicate to master. For similar reasons, nanoparticles are intrinsically unstable and may easily heterogeneously or homogeneously aggregate, chemically transform and corrode and disintegrate. To be exposed to biological systems, for a nanoparticle, it suffices to have few albumin proteins absorbed onto it and then they can be introduced in physiological environments where many are dissolved and metabolized. In principle, it has been observed up to now that cells deal easily with tiny particles, and no significant acute toxicity has been found in in vitro and in vivo studies at realistic doses, unless toxic components were present in the formulations.43

At the origin of nanotoxicity and nanosafety concerns, it was pointed at the well-known fact that cells have problems dealing with micrometric insoluble particles. Asbestos fibers, with dimensions greater than 20 micrometers, up to hundreds, induce frustrated phagocytosis43, chronic inflammation, asbestosis, and years later, cancer. This is not the case for small, sub-micrometric particles. A concern then was if small NPs could accumulate and aggregate up to such dangerous sizes. In this regard, NP dose and persistency are key to determine this potential risk. If the

42 Harald F. Krug Angewandte Chimie 2014, 53, 12304-1231
NPs do not aggregate, they may dissolve. When they dissolve they yield ions (metal cations) that may be toxic, as in the well-known case of cadmium or silver NPs. In parallel, the corrosion process is a redox active process that may stress the cell environment. However this effect has been observed to be transient and only significant at rather high doses. Therefore, regarding nanotoxicity, and the associated risks to work with NPs, current knowledge indicates that many NPs in their intended uses do not need special care beyond being treated like other chemical substances, even if some particularities may apply. Nanotoxicity is a young field that can be considered to be about 10 years old. Despite this youth, much knowledge from metal toxicity, microparticle toxicity (sarcoidosis, asbestosis, silicosis), environmental pollution and other disciplines have contributed significantly to the rapid establishment of the nanosafety discipline. It is also important to be aware that simple nanoparticulate materials have been used in consumer products for a long time, as food additives (E-171 to E-175 have a nanometric portion of iron oxide, aluminium oxide, titanium dioxide, silver and gold, respectively), in cosmetics, as simple as talc, catalysts, paint pigments, coatings and others. Up to now, we have been mainly reproducing nanomaterials that already exist in nature or that somehow are already produced by man in a more imperfect and unaware manner. Small, (about 20 nm) iron oxide NPs have been found in natural unpolluted soils or inside bacterial magnetosomes, and nanometric TiO₂ has been used by the tonne in the cosmetic industry as sun screens and other formulations for decades now. When we get the next generations of nanoparticles, additional care will need to be considered. Before that, and as no acute effects have been observed or identified, more subtle effects will need to be investigated. Also, these results are related to healthy conditions and acute doses. Thus, despite the absence of signs of alarm, it is desirable to perform long term studies at chronic and subtoxic doses and in compromised states (when the body is weakened by disease). Alterations of the immune system and changes in biodistribution in the case of inflammation might exacerbate or suppress acute effects and accumulate in organs (if the NPs succeed in entering the body, which is very unusual, even after dermal contact or ingestion). Thus, chronic exposure at subtoxic doses, long term effects, repeated doses, or co-exposure of different types of NPs and other toxins (such as LPS, allergens or chemical toxins), or exposure to NPs in the case of disease, e.g.: during cirrhosis may be more critical and need to be studied. Focus has to be put also on the immune system, which is responsible for detecting, categorizing and managing external invasion. The immune system has memory, so repeated exposure to NPs could alter immune response.

Nanoparticles may exist in different forms during their full life cycle, normally: pristine (as synthesized), functionalized (ready to be used and during use), disposed and degraded (after use). The exposure and biological effects depend on the state of the NP at each point of their life. Iron oxide nanoparticles have not been found toxic in any of these forms unless they were functionalized with toxic moieties.

While it has been observed that NPs do not penetrate the skin and are not up-taken after ingestion, concerns remain with respect to pulmonary exposure. It is the ability of small dry NPs to be aerosolized from dry powders and enter the lungs. Experimental studies in animals have shown that at equivalent mass doses, poorly soluble nanostructured metal oxides in the form of agglomerated or aggregated nanoparticles (e.g., titanium dioxide, aluminium oxide, and manganese dioxide) are more potent in animals than equivalent single well dispersed particles of similar composition in causing pulmonary inflammation and tissue damage. For these and other poorly soluble particles, a consistent dose-response relationship is observed when dose is expressed as particle surface area. These animal studies suggest that for nanostructured materials and larger particles with similar chemical properties, the toxicity of a given mass dose will increase with decreasing particle size due to the increasing surface area. Therefore, the breathing of solid nanoparticles, especially aggregates made of persistent materials, is highly unadvisable. However, even for poorly soluble particles of relatively low toxicity, animal studies have identified doses that were not associated with observed adverse responses. For example, a recent animal study reported mass doses of either fine or nanostructured TiO₂ in rats at which the lung responses did not significantly differ from controls, while crystalline silica caused more severe lung responses at the same mass dose. In addition to particle size and surface area, other physical and chemical properties of particles are known to influence biological interactions, including solubility, shape, surface reactive sites, charge, and crystal structure. Note that this is not the case for BioGAS⁺ which is made of non-persistent NPs; they are not aggregated and they do not carry toxic moieties or toxic additives or toxic excipients.

In the following the main causes associated to NP induced toxicity are listed. In principle, at realistic doses in a controlled manner, inorganic NPs have basically shown toxicity due to aggregation or dissolution, or because they were carrying toxic moieties.

i.- Toxicity has been observed in the case of some cationic (positively charged) NPs. This is well known for both biological (antimicrobial peptides) and micrometric (organic) particles where cationic charge at their surface makes them interact strongly with cell membranes, thus interfering with its normal functioning and inducing cell death. See for example Chitosan functionalization of gold nanoparticles.\(^{48}\) This charge is carried by molecules attached to the surface or by the inorganic surface itself if it is at pHs lower than the NP isoelectric point, although toxicity has only been observed when the cationic charge is maintained in the physiological media. In the case of BioGAS+, it is prepared at basic pH displaying a negatively charged surface which becomes neutral when dispersed in the working environment. At acidic pH, where the BioGAS+ NPs would present positive surface charge, they dissolve.

ii.- Toxicity has been related to aggregation. Aggregates caused direct acute toxicity when mice were intratracheally instilled with carbon-nanotubes, and they suffocated due to tracheal clogging, indicating the poor dispersability of hydrophobic nanostructures in biological systems.\(^{49}\) Risks have also been observed in the case of penetration of non-biodegradable persistent micrometric particles (in principle bigger than 20 micrometers) in the lungs and related with frustrated phagocytosis and the onset of chronic inflammation, as in the case of silicosis, granulomatosis and asbestosis. When a strange object is detected by the immune system, and not categorized as danger, it is simply phagocytized and removed away from the biological machinery whether denaturalized protein aggregates or cell debris. This applies for nanoparticles (3 to 100 nm), viruses (20-400 nm), bacteria (~1000 nm), and eukariota cells (~10.000 nm). However, when the object is too big (beyond 10 micrometers),\(^{50}\) the immune cells cannot engulf it and then triggers a chemical defence against the non-biodegradable material. This leads to tissue irritation and in the long run, may cause cancer. Needle-like microparticles such as asbestos 10 x 500 microns, are especially effective to induce this effect.

In determined conditions, NPs could aggregate to micrometric sizes. But as the size increases, the likelihood for exposure and particle penetration also decreases. There are many strategies to avoid aggregation developed for decades in different fields of material science and chemistry. There are two simple ways to avoid aggregation; to avoid high concentrations (if there are few NPs, it is difficult for NPs to meet to grow and form an aggregate), and to use anti-aggregation agents. Aggregation is a phenomenon thermodynamically favored, driven by the reduction of the high energy surface of the nanoparticles. Absorption of molecules which provide electrostatic charge or steric repulsion to the nanoparticle serve to maintain their isolation even at high concentrations. In complex media it is observed that nanoparticles are rapidly coated by molecules from the environment, their surface energy decreased and their tendency for aggregation cancelled. In the case of BioGAS+ only when the material is prepared is there is risk of aggregation, and none once they have been dispersed in the working environment. Likely, when inorganic NPs are dispersed in serum they are rapidly coated by proteins (forming the so-called protein corona) which avoids their further aggregation, which would always be a subject of concern. Also, aggregation can be programmed, for example as a way of disposal, producing aggregates which are larger than the micrometric critical size and easily operable as bulk materials.

iii.- Toxicity has been related to breathing dry (powdered) nanoparticles (and its aggregates). Fortunately, NPs do not cross the skin and do not get inside the body from the intestinal tract (humans have been eating soil for millennia and naturally small NPs form and dissolve or aggregate constantly). The critical point here are clearly the lungs, even if the mucociliary escalatory system may be effective in removing foreign matter from the lungs (especially small NPs). Therefore, it is not recommended to be exposed to nanoparticle aerosols, and for that reason, it would be enough to avoid working in the dry phase. Wet NPs do not leave the solution, they stay in the liquid body and are not transferred to the atmosphere; if the drop is dried they aggregate and stick to the substrate. In a study of chemical contamination in the laboratory by electron microscopy and ICPMS, dispersion of the NPs from the liquid phase was not observed. The conclusions were that once the NPs have been somewhere, a tiny residue remains for ever even after washing (similarly with ions) but that there was no cross-contamination, even at extreme proximity from the vessels and vials that contained the solution. The ambient filters and air purifiers were empty of observable NPs (other than the micrometric particles of dust), concluding that the NPs cannot leave...

48 Chitosan functionalisation of gold nanoparticles encourages particle uptake and induces cytotoxicity and pro-inflammatory conditions in phagocytic cells, as well as enhancing particle interactions with serum components. Journal of nanobiotechnology 2015, 13 (1), 84.


from the wet phase. At the same time, it has been observed that ultrafine powders of nanoparticles are easily aerosolized and transported long distances.

iv.- Toxicity has been observed when the NP act as a reservoir of toxic ions that are delivered during corrosion. The paradigmatic case is CdSe nanoparticles which become more toxic with time, as they corrode and yield Cd ions. Indeed, to dissipate surface energy, if the nanoparticles do not aggregate or associate with coating molecules, many of them will disintegrate. This is a common phenomenon in nature and widely studied by geochemistry where a nanoparticle is an intermediate state between the micrometric particle and the dissolved ions. Or, like in microbiology, where bacteria synthesize small inorganic nanoparticles of toxic ions to detoxify the environment. Changes in the surroundings when the nanoparticle leaves the synthesis environment lead many NPs to disintegration, by corrosion and other chemical transformation that dissolves it. In this process the NP yield ions, and also may yield electrons. Electrons are reactive and generate reactive oxygen species (ROS) which may be toxic if sustained for a long time (if the stress causing the response is maintained). Metallic cations are often bioactive, for example, cadmium, mercury and lead cations are very toxic to us, nickel is allergenic, cobalt is carcinogenic, silver cations are toxic to bacteria, and copper ions are toxic to fungi (and fungi are toxic to bacteria). Besides, iron is a common ion in biological systems at very high concentrations. Indeed, the slow dissolution of iron oxide NPs into iron ions has made iron NPs an active principle (feromuxyto) to treat ferroenic anaemia, controlling the dosing at the molecular level. Basically, the pattern of exposure, the dosing profile, is different when using the ionic species directly, or when these are provided by a dissolving NP (acute vs sustained dosing).

v.- Toxicity has been related to the capacity of NPs in presenting antigens or allergens. NPs can be good aggregators and orientators of molecules to be presented to the immune system. Indeed, nanoparticles are excellent molecular carriers and a whole scientific field is developing around it, which could be a cause of major concern if functionalizable nanoparticles were dispersed in the environment and unfortunately associated with antigens or allergens before homogeneous or heterogeneous aggregation. For example, when car combustion emission microparticles are coated by pollen grains, they become more allergenic. This is one of the reasons why allergies in urban areas are more intense than in the countryside. Therefore, the NP surface has to be passivated before being uncontrolledly dispersed. Fortunately, the concentration of toxins and allergens in the environment in comparison with the rest of the inert or tolerable molecules is very low and the promiscuity of the nanoparticle surface very high, so it would be unlikely that naked nanoparticles meet toxins, antigens or allergens before their surface is passivated by other molecules.

vi.- Toxicity has been associated also with catalysis, especially in the case of photocatalysis with NPs as TiO$_2$ that are able to generate toxic free radicals when illuminated. Catalysis is a surface phenomenon, and the high surface to volume ratio of small nanoparticles has been exploited for years in the chemical industry. Despite the natural suitability of inorganic NPs for catalysis, it is well known that it is unexpected that NPs will act as powerful catalysts unless they are designed to do so. Indeed, normally, nanoparticle surfaces are rapidly passivated with organic molecules that interface the inorganic core with the environment. Lacking that protecting layer, nanoparticle life is extremely brief and they absorb irreversibly or vanish. In this case, the protecting layer dumps the catalytic powers of the inorganic nanoparticle. This is the case of TiO$_2$ coated with a thin transparent layer of Al$_2$O$_3$ in sunscreens. The TiO$_2$ is still able to absorb the high energy photon, but the electron thus generated is buried at the bottom of the conduction band of TiO$_2$, which is a material that does not absorb UV light. Therefore, the unintended mix of detergents and NPs it seems inadvisable. Note that detergents are already poorly biocompatible, although fortunately they are normally highly biodegradable.

vii.- Toxicity has been related to hydrophobicity, and since hydrophobic substances hardly disperse in biological environments, attention has to be paid to amphiphilic or detergent-like molecules that can be transported by NPs, such as in the well-known case of gold NPs coated with a cationic detergent like CTAB. This detergent forms a double layer vesicle-like coating on the NP surface and can be dispersed in biological environments and then, in contact with cells, they may expose their hydrophobic core to the cell membrane (which has also a vesicle like structure with an inner hydrophobic core), perturbing it. These are similar effects to those observed with pure detergent molecules; however, it would happen at lower detergent doses in the case of association to NPs. Therefore the unintended mix of detergents and NPs it seems inadvisable. Note that detergents are already poorly biocompatible, although fortunately they are normally highly biodegradable.

viii.- Toxicity can be observed if tissue is irradiated when nanoparticles are present. The only toxicity related to irradiation of a NP containing body is related to the increased dosing of the received radiation. Therefore one

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51 Homogeneous conjugation of peptides onto gold nanoparticles enhances macrophage response ACS nano 2009, 3 (6), 1335-1344
52 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2988217/
should not be exposed to radiation, magnetic hyperthermia in the case of superparamagnetic nanoparticles, or x-ray radiotherapy in the case of heavy metal nanoparticles. Note that for MRI imaging superparamagnetic nanoparticles are used as safe contrast agents.

All this knowledge allows us to work under nanosafety by design paradigms. Safety by design, from its definition, is a concept and movement that encourages construction or product designers to "design out" health and safety risks during design development. The concept supports the view that along with quality, program and cost; safety should be determined during the design stage in order to avoid development of technologies that result in being unsafe once they are already developed. Otherwise, we will suffer until the technology is forbidden, after problems have already been created, and the environment, polluted for decades.

Thus, risk mitigation methodologies can be developed and implemented taking into consideration the whole life cycle of a nano-enabled product. Innovative safer-by-design approaches beyond surface modifications can be designed, taking into account all the existing information on structural features that determine NPs' toxicity, release and degradation. In the case where hazards are found, NPs have to be re-designed so that detrimental specific NP characteristics are decreased while maintaining the desired unique intended parental properties. These strategies should not only focus on reducing NP hazards, but on reducing NP release from matrices or promoting their degradability after release.

**To reduce toxicity of the NPs.**

Shape and size modifications.

Increase in hydrophilicity to decrease the potential to cross biological membranes.

Increase in lipophilicity to promote aggregation and precipitation.

Modification of the intrinsic bulk composition of NPs or changing oxidation state to mitigate reactivity.

Design NPs that lose their catalytic activity when released from their embedding matrices

**To minimize release of NPs from their matrices.**

Induction of strong van der Waals and covalent bonding between the NPs and their matrices.

Development of barriers by multilayer approaches involving development of multilayer films, or multicoating approaches.

Self-healing pairs of NP / matrix by developing a suitable ionic approach to improve the formation of ionic bonding inside the host.

Induction of self-assembly of NMs in aqueous media or at high temperatures by introducing labile or different functionalities to increase the coalescent character of the NPs (sintering).

**To reduce persistence of NPs**

Development of new high biodegradable NPs under certain temperature or oxidative conditions.

Modify oxidation state of NPs.

Introduce impurities to increase the instability and degradability of NPs.

**Table 1. Safety by design approximation extracted from GuideNANO (www.guidenano.eu)**

In addition to safer-by-design approaches, best practices for handling / packaging, different levels of confinement, and use of general exposure control measures and personal protective equipment (PPE) have to be included. The protection factors towards NPs for existing PPEs have yet to be fully evaluated, but in principle, protection against chemical substances does work for protection against nanoparticulate matter. When necessary, technological solutions have to be developed for exposure reduction and PPE (e.g., selecting less permeable materials, introducing double layers, use of nonwoven fabrics, and ventilated/pressurized systems). Depending on the efficiency of different exposure reduction technologies available, technological improvements in water and air filtering (e.g., foam technology) and treatment (destruction of NPs) may need to be developed.
3. The development of new rehabilitation devices for use in the community setting - the Rehab Angel

JIM RICHARDS

The main output for this case study is a video, which is supplemented by a short case description.

Please click here for the case videos:
https://innovation-compass.eu/cases/

3.1. Executive Summary

This case study is about a collaboration between a university partner and an SME. The output of the collaboration is the Rehab Angel, a commercially available angle device used mostly for knee rehabilitation purposes.

The key driver for the university research was to provide clinicians with robust tools that they can use to evaluate, treat and therefore improve the clinical outcome in their patients. The research has assisted the development of the evidence base of many clinical treatments and assessment tools. This has led to the design and development of new rehabilitation products and medical devices in partnership with both large companies and small to medium sized enterprises.

The example used in this case study came from research on the exploration of the biomechanics of squatting tasks and the implications for lower limb rehabilitation. Single-limb squats on a decline angle have been suggested as a rehabilitative intervention to target the knee extensors, however very little empirical research existed documenting the optimum angle of decline, with most clinicians using a single angle of 25 degrees, Figure 1. Extensive research showed that different flexible angles were more
beneficial for the patients, which led to the development and commercialisation of the Rehab Angel.

3.2. Research and the Product

Work undertaken at the Allied Health Research unit, University of Central Lancashire UK, identified a lack of evidence of the exact nature and “dosage angle” of interventions used by clinicians. The research group then explored the use of squatting using decline boards and aimed to determine the optimum angle and the most effective regimen. A paper, published in the *Journal of Athletic Training* (Richards et al, 2008), was the first to determine the biomechanics of such exercises, and suggested the optimum angles for different rehabilitation purposes.

The university was subsequently involved with prototype development and providing further proof of concept testing for the final commercially available product. This has led to the publication of “The effect of different decline angles on the biomechanics of double limb squats and the implications to clinical and training practice” (Richards et al, 2016), Figure 2.

![Figure 2: New rehabilitation device, the “Rehab Angel”](image)

The aim of this study was to determine the loads around and on the ankle and knee joints and muscle activity while performing a “squat” (a common physiotherapy task) to highlight the benefits and implications to rehabilitation. Eighteen healthy subjects performed double limb squats at six angles of declination: 0, 5, 10, 15, 20 and 25 degrees. The range of motion of the knee and ankle joints, joint loads and muscle activity of the gastrocnemius (calf muscle), tibialis anterior (front of the lower leg), rectus femoris (quadriceps) and biceps femoris (hamstring) were evaluated. As the decline angle increased up to 20 degrees, the range of motion possible at the ankle and knee increased. The joint loads showed a decrease at the ankle up to a 15 degrees decline and an increase at the knee up to 25 degrees decline, indicating a progressive reduction in loading around the ankle with a corresponding increase of the load in the patellar tendon and patellofemoral joint. These trends were supported by a decrease in tibialis anterior activity and an increase in the rectus femoris activity up to 15 degrees decline. However, gastrocnemius and biceps femoris activity increased as the decline angle increased above 15 degrees. These findings suggested that there is little benefit in using a decline angle greater than 15-20 degrees unless the purpose is to offer an additional stability challenge to the knee joint and that the use of graduated exercise maybe better than a fixed angle.
This work led to the development of a new rehabilitation device, the “Rehab Angel”, which allows the decline angle to be adjusted based on our findings (Richards et al, 2008), in cooperation with Medical Devices Technology International Limited (MDTi).

3.3. Stakeholder collaboration
The Rehab Angel was the product of collaboration between a range of stakeholders, in particular UK National Health Service, academia and industry. The three groups formed a team with the purpose of developing a new device that could provide a graduated rehabilitation. These partners brought in their collective expertise in order to allow knowledge exchange and rapid development of a new rehabilitation device. This collaboration removed many of the latent issues around the innovation pathway, since key knowledge holders and product production systems were brought into the delivery of the project from the outset. The purpose of this innovation was to provide a low cost, readily accessible evidence base for the rehabilitation device, which could improve care and outcomes through patient physical rehabilitation in the community setting.

3.4. Industry Benefits
The Rehab Angel aims to assist patients to better assess and undertake exercise regimens before and after appointments with healthcare professionals, therefore improving clinical utility and productivity.

This aforementioned collaboration aimed to address a clinical need and with an industry focus to create a new product that could be supported by evidence to allow more effective marketing and a greater understanding of a rehabilitation exercise.

This case study shows that an SME led technology innovation, when linking with a university, can gain important independent testing. The SME involvement allowed a real world output, in the shape of a new rehabilitation device that linked theoretical research and enhanced clinical understanding. This collaborative R&D project supported the SME in:

a) proof of market, through an understanding of current clinical practice;
b) proof of concept testing, through testing of the effect of adapting the rehabilitation exercises (Richards et al, 2008);
c) the development and testing of the final prototype (Richards et al, 2016); and
d) provided independent reports and peer review papers to allow “evidence based” marketing and purchasing.

This project, funded through National Health Service (NHS) innovation and European Regional Development Fund (ERDF) innovation helped the SME access knowledge, testing and development services, which increased the ability of the SME to innovate and commercialise the new rehabilitation device. Thereby greater levels of innovation in all sectors of the economy were encouraged, with the longer term goal of driving economic growth and creating jobs, whilst improvement rehabilitation within the clinical environment.

The Rehab Angel is now commercially available and is being used in many rehabilitation centres and professional sports clubs in a variety of knee and other lower limb pathologies. The core impact of this work has been positive developments in patient care and quality of life. This case study shows that an SME led technology innovation, when linking with a university can gain important independent testing.
by improving the efficacy and effectiveness in these areas, with a particular focus on the advancement of conservative management and lower limb rehabilitation.

3.5. **Why does this case fall under RRI?**

Using the key action points of RRI developed by the Science with and for Society unit:53

- engage society more broadly in its research and innovation activities,
- increase access to scientific results,
- ensure gender equality, in both the research process and research content,
- take into account the ethical dimension, and
- promote formal and informal science education.

This project high-lights the benefits of stakeholder collaboration (societal engagement) and more importantly the benefits of informal science education to the economy, given the considerable knowledge transfer from the university to the SME, which commercialized the Rehab Angel.

3.6. **References**


4. Telemedicine for diabetes care – the case of GlucoTel™

KARSTEN BOLZ

4.1. Executive Summary

This case study takes a look at telemedical applications in the area of diabetes care through the case of GlucoTel™, a telemonitoring system developed by BodyTel™. It links the company's activities to aspects of Responsible Research and Innovation (RRI) such as addressing societal challenges, stakeholder engagement, legal requirements and open access. In addition to describing the relationship between the telemedical diabetes monitoring system from BodyTel™ and RRI activities of the company, this case study also takes a global perspective into account.

The number of people with diabetes worldwide is projected to increase from 171 million in 2000 to 366 million by 2030. Diabetes is not only a challenge for Europe or the USA but also for low and middle income countries. It is a global societal challenge which is connected with health complications, secondary diseases and skyrocketing costs for health care services as well as absenteeism from the workplace.

Telemedicine provides an integrated approach for patients and caregivers with efficient tools to support their daily tasks in diabetes care. As part of the BodyTel™ system, GlucoTel™ is such an approach. It is a sensor for telemedical blood glucose monitoring and diabetes management and is used for automatic, continuous documentation of all blood glucose levels. It is part of the three-stage BodyTel™ system which consists of a measuring device with Bluetooth technology, an app for mobile phones and tablets, and an online diary which is connected to the secure Medical Data Cloud where all data is stored.

BodyTel™ and its devices and services are certified regarding EN ISO 13485:2012 and ISO 15197:2015 to meet legal requirements for medical devices. In 2012 the company became part of the Continua Health Alliance to follow an open access approach which allows a standardized interface for higher compatibility with other products and services. Furthermore, BodyTel™ engages stakeholders such as patients and caregivers during its development processes to improve the treatment of chronic diseases and contribute to higher quality of life for patients. It also contributes to building an overall standardized telemedical system, which allows a better and more efficient treatment of chronic diseases such as diabetes.

All these activities are closely connected to the RRI approach and not only benefit patients and caregivers but also the company itself. The feedback gathered throughout engagement activities allows BodyTel™ to improve the usability of their devices which is key for the success of such solutions. Furthermore, contributing to the development of an overall standardized telemedical system allows BodyTel™ to set parts of this standard, and could guarantee great
competitive advantage through lock-in effects. Also, the open access approach with the Continua certification benefits the company, leading to better cooperation and the establishment of new partnerships as well as cost savings.

Overall the case study shows that integrating RRI principles into company processes not only benefits users – in this case patients and caregivers - but can also have great benefits for the company, e.g. by guaranteeing competitive advantage.

4.2. Field of Industry or Service

4.2.1. Diabetes as a global societal challenge

Diabetes mellitus, commonly referred to as diabetes, is a group of metabolic chronic diseases characterized by a sustained elevated blood glucose level, which is caused by a reduction in the action of insulin secretion where related metabolic disturbances generate severe, acute and long-term complications and secondary disease that are responsible for premature death and disability.¹

In Western societies, diabetes and its complications are causing a great amount of suffering and continue to be a major health problem which leads to as much as 8% of national spending in health care.² It is rapidly emerging as a global health care problem that threatens to reach pandemic levels by 2030.³ The number of people with diabetes worldwide is projected to increase from 171 million in 2000 to 366 million by 2030.⁴ The increase can be observed in high income settings such as Europe or the USA but will mainly occur in low or middle income countries (LMICs). This shows that diabetes, which is often caused by being overweight or obesity, is not only a challenge for Europe or the USA but can be seen as a global challenge (see figure 1³). Also the incidence and prevalence of diabetes among children are increasing at an alarming rate, with potentially devastating consequences. This increasing number of diabetes patients is a huge challenge when it comes to being a healthier society and is connected with skyrocketing costs for health care services.

Nowadays, a well-treated insulin-dependent diabetic patient can expect to have an almost normal life span due to the benefits of intensive management reducing long-term complications.⁵ Nevertheless, the achievement of the therapeutic goals implies a significant increase in the amount of patient data to be monitored.² The basis of diabetes therapy and the therapy approach itself are diaries, written by patients or their nurses: a regular obligation with many potential sources of error. The consequences can include dosing errors, bad
metabolism, as well as deviations from treatment recommendations, all of which can result in avoidable secondary complications. These errors often lead to in-patient stays connected with high costs such as hospital costs but also absenteeism from work.

For the last two decades, diabetes has been a major clinical focus for advances in information technology such as telemedical applications. Telemedicine provides an integrated approach for patients and caregivers to support their daily tasks in diabetes care. This is a fundamentally different healthcare model, particularly in the way healthcare is delivered. A main goal of telemedical diabetes care is to minimize potential sources of error and optimize treatment to reduce the risk of secondary disease and other complications. From an economic point of view such solutions could help ensure savings in care and nursing services.

### 4.2.2. The GlucoTel™ system

GlucoTel™ is a sensor for telemedical blood glucose monitoring and diabetes management. It is used for automatic, continuous documentation of all blood glucose levels and is part of the three-stage BodyTel™ system, consisting of a measuring device with Bluetooth technology, an app for mobile phones and tablets, and an online diary (see figure 2).

![Figure 2: The GlucoTel™ System (Source: BodyTel™ GmbH)](image)

BodyTel™ is a German telemedicine company which has developed a comprehensive monitoring and management system for chronic illnesses. The aim is to provide patients and persons authorized by patients (e.g. medical professionals or family members) with the most up-to-date and precise information that is possible about the patient. Decisions about changes of treatment can thus be made more quickly, secondary illnesses can be minimized, and quality of life can be improved.

GlucoTel™ addresses a variety of users. For example **parents of affected children**, who want to know, if the child performed the necessary blood glucose measurements and about the measurement’s value. Through the GlucoTel™ system, they can be informed about any measured value automatically. But **people of all ages** can benefit from the GlucoTel™ system by not having to manually document their measured values anymore. An online diary stores all values and can be printed out before seeing the doctor, or more generally shared with the caregiver. Additionally, **people who worry about elderly dependents can also** take

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54 All information about the product and the company is taken from the company website: [http://bodytel.com/?lang=en](http://bodytel.com/?lang=en).
advantage of the system. The GlucoTel™ system can help older generations with diabetes to live an independent life for longer. Also medical caregivers such as physicians or diabetes advisors benefit from the GlucoTel™ system. The automatic and complete data storage provides seamless documentation. With the authorization of the user, caregivers can access the diary and provide direct feedback. This may reduce unnecessary doctor visits, and questions can be clarified on the phone.

All values measured with BodyTel™ devices are sent wirelessly via Bluetooth through a cell phone or home gateway into the patient's online record. All patient records are located in BodyTel™’s secure Medical Data Cloud, which is part of the medically approved overall system. All patient data remains the exclusive property of the patient, who has access to these values in their personal online record. With the optional monitoring function the patient alone may permit third parties (e.g. doctors or family members) to view the record. Caregivers can independently decide whether they want to receive real-time alerts via text message, e-mail or fax for every incoming measurement value, only for unusual ones, or none at all. These authorized monitoring rights can be withdrawn any time by the patient. The online diary provides comprehensive displays and summary functions. It enables doctors or medical caregivers to monitor and control the measurement behavior of a large number of patients.

4.3. Event or Activity

4.3.1. The BodyTel™ ecosystem & stakeholder engagement

During the development of products and services the BodyTel™ team addresses a wide variety of stakeholders to develop tailored solutions. The BodyTel™ ecosystem includes five major groups:

- **Patients & family**
  
  The main stakeholders of BodyTel™ are patients and their families, as its solutions address people suffering from diabetes who want to better document their health data and control their chronic disease. Furthermore BodyTel™ provides solutions for people, who want to care for their family and friends, who suffer from chronic diseases such as diabetes. This might happen in the case of school children, grandparents, or friends living far away.
• **Caregivers & medical advisers**
  Another key stakeholder group is made up of caregivers and medical advisers, who can use the BodyTel™ system to obtain complete documentation and, if authorized, observe the parameters of their patients. This way, physician visits can be reduced, and smaller problems cleared up on the phone, without the necessity for the patient to visit the doctor’s office personally.

• **Health insurance companies**
  As a large share of the costs of the health system is caused by the treatment of patients with chronic diseases such as diabetes, insurance companies are another important stakeholder. The use of telemedicine can improve the treatment of patients and reduce costs, as problematic values can be detected faster, avoiding costs for regular doctors’ visits. Thus, telemedical care programs can offer competitive advantages for health insurance companies.

• **Medical technology & pharmaceutical companies**
  For medical technology or pharmaceutical companies telemedicine has the potential to open up new market opportunities. They can position themselves with innovative products and use telemedicine and telemonitoring to become full-service companies.

• **Integrators of sensors and services**
  By providing an interface description of the telemedical blood glucose meter, as well as offering partners the ability to connect their solutions with our Medical Data Cloud BodyTel™, GlucoTel™ creates the opportunity to easily integrate new products or services which benefit customers and patients.

During the development of products and services BodyTel™ interacts with different groups of stakeholders. As BodyTel™’s focus is on the development of medical devices and services, patients and caregivers are of crucial relevance. According to Michaela Klinger, Head of Marketing & Business Development Manager of BodyTel™ GmbH, patients and caregivers often provide usability improvement hints during the project phase, in which devices are tested on a smaller scale. The feedback is collected and handed over to the development department for implementation to improve the devices and services. In the case of GlucoTel™ this happened during an ‘Einsteigerprogramm” in which BodyTel™ gave away compatible mobile phones including BodyTel™ SIM cards to patients, who agreed to answer a product questionnaire every three months. In this way BodyTel™ has collected a lot of feedback over the years.

Besides engagement during the development phase of products and services, BodyTel™ also collaborates closely with other actors in the field when it comes to the secure Medical Data Cloud and mobile App. At MEDICA 2015 BodyTel™ presented an overall solution for a standardized electronic health data infrastructure in cooperation with Cisco Systems, Parsek and Tiani Spirit. This makes the health data measured with the GlucoTel™ system available for the German telematic infrastructure. This enables the first European IT-system, which meets the criteria for standardized electronic patient data and enables the transfer of blood

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55 Einsteigerprogramm (German) means program for novices.
glucose values or other health data measured at home via the mobile app and the Medical Data Cloud to established IT-systems in hospitals and doctors’ offices.\(^\text{10}\)

Overall, one could state that the engagement activities of BodyTel™ have two major goals: First, to improve their products and services, which guarantees BodyTel™ a competitive advantage, and second, better usability for patients, caregivers and other users, which improves the treatment of chronic disease, improves the acceptance of new tools and helps to save health care costs.

Regulators also play a role as medical products are required to meet specific criteria to be sold on certain markets. BodyTel™ addresses this demand by certifying its processes and products according to industry standards as outlined below.

### 4.3.1. Certifications

BodyTel™ GmbH is certified regarding EN ISO 13485:2012 in the areas of the design, development, production and running of medical software (mobile Apps and online portals) for the management of health data, as well as services and trade of medical devices. EN ISO 13485 represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices, and is tailored to the industry’s quality system expectations and regulatory requirements. In addition to this general certification of the company, the GlucoTel™ system is certified regarding ISO 15197:2015, which specifies requirements for in vitro glucose monitoring systems that measure glucose concentrations in capillary blood samples, for specific design verification procedures, and for the validation of performance by the intended users. These systems are intended for self-measurement by lay persons for management of diabetes mellitus. ISO 15197:2015 ensures certified systems meet specific criteria when it comes to performance.

Besides these two ISO certifications, which can be seen as a first step in achieving compliance with regulatory requirements, BodyTel™ joined the Continua Health Alliance\(^\text{56}\) in 2012,\(^\text{11}\) which is dedicated to:

> [p]romote the adoption, standardization and appropriate regulation of personal connected health devices and systems in order to empower individuals to better manage their health and wellness from anywhere, at any time, with stronger links between consumers, their social networks and providers.\(^\text{12}\)

Continua promotes its own standard for the transmission of medical data based on the Bluetooth health device profile (HDP), which allows the compatibility of Continua certified devices and systems. The goal is to benefit customers and patients through a greater variety of products and services compatible with each other, and allow the integration of a wide variety of sensors into the BodyTel™ Medical Data Cloud.

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\(^{56}\) The Continua Health Alliance is part of the Personal Connected Health Alliance (PCHA): [http://www.pchalliance.org/continua](http://www.pchalliance.org/continua)
4.4. Why does this fall under RRI?

Health, demographic change and wellbeing is one of the societal challenges defined by the European Commission in the ‘Horizon 2020’ program which reflects the policy priorities of the Europe 2020 strategy. Addressing societal challenges through innovation is part of Responsible Research and Innovation (RRI), as defined, for instance, by Rene von Schomberg. Von Schomberg emphasizes the societal desirability element of RRI, when he argues that research and innovation have to bring “the right impacts and outcomes”\textsuperscript{14}. This also becomes evident by taking a look at the definition of RRI given by the European Commission:

RRI is an inclusive approach to research and innovation (R&I), to ensure that societal actors work together during the whole research and innovation process. It aims to better align both the process and outcomes of R&I, with the values, needs and expectations of European society.\textsuperscript{15}

Inclusion is one of the most important dimensions addressed by RRI. In an industry setting this means companies should engage stakeholders throughout their innovation process and collaborate closely with them. By engaging a diversity of stakeholders during the innovation process aspects of sustainability, acceptability and desirability of products and services should be taken into account. But RRI is not exclusively about coping with societal challenges and collaboration; it also takes other aspects like legal requirements or open access into account.\textsuperscript{16}

As described above, diabetes is a threat not only in Europe or the USA. It can be seen as a global societal challenge which needs to be addressed through innovative solutions. Hence telemedical programs can be found both in Western countries as well as in LMICs. Especially in rural areas telemedicine can help to improve the treatment of diabetes. The Chunampet Rural Diabetes Prevention Project is an example of such a program. It was conceived with the aim of implementing comprehensive diabetes screening, prevention, and treatment using a combination of telemedicine and personalized care in rural India.\textsuperscript{17} Although the project uses a combination of telemedicine and personalized care, it emphasizes the potential of telemedical applications in rural areas. In general, LMICs have good preconditions for implementing telemedical diabetes care programs as there is an increasing number of people with access to mobile internet and mobile phones. Figure 4 (next page) shows this rapid development for countries in which 2015 GNI per capita was $12,475 or less, including countries like China and India, which are assumed to be highly affected by the increase of diabetes (as figure 1 shows).

The potential for telemedical applications is high as it allows more efficient care due to a better patient–medical advisor ratio, and lower complications and secondary disease rates. This allows a better quality of life as well as cost savings for health care and nursing. From an economic point of view this is an important factor, especially for LMICs which face great challenges in providing health care services. When telemedical applications can be made accessible and affordable to the countries most affected, then telemedicine has great potential to help in solving the global societal challenge of diabetes care.
From this macro scale of RRI to the micro level, BodyTel™ follows several aspects of RRI in its activities. First, the company engages stakeholders such as patients and caregivers during the development processes to improve the treatment of diabetes, which contributes to higher quality of life for patients. Second, it complies with legal requirements through ISO certifications. And third, BodyTel™ follows an (partly) open access approach when it comes to its interface technology through the Continua certification. Besides the fact that BodyTel™ engages with stakeholders, complies with legal requirements and follows an open access approach, most importantly BodyTel™ contributes to building an overall standardized telemedical system which allows better and more efficient treatment of chronic diseases such as diabetes, which are global societal challenges.

4.5. What are the benefits for industry?

The main benefits for BodyTel™ of the activities outlined above can be described as follows. Overall, the integration of different stakeholders during the development of products and services improves the usability of their devices, which is key for the success of such solutions. In this context, Michaela Klinger stated that through the feedback provided, BodyTel™ is able to make the tools both more usable and smarter which encourages doctors and nurses to monitor patients more closely. In addition, she added that the improvements that can be implemented in the project phase are often beneficial for everybody; for BodyTel™ to improve the product, for caregivers to effectively monitor patients, and for the patients, who feel they are in good hands. The feedback gathered throughout engagement activities allows BodyTel™ to further develop their products, and thus is able to improve the monitoring process, which benefits patients and caregivers as well as the company itself.

User feedback is most valuable. They are the ones working with the stuff we develop on a daily basis and they face problems much faster and in a higher intensity than we
could ever imagine. This feedback was the most important one. If you are not listening to what they have to say you are developing stuff for yourself but not for the people.9

Another benefit resulting from the close collaboration with stakeholders can be seen in the contribution to the development of an overall standardized telemedical system, which allows BodyTel™ to set parts of this standard, and could guarantee great competitive advantage through lock-in effects. Furthermore, the open access approach through the Continua certification not only benefits customers and patients through a greater variety of products and services compatible with each other, it also helps BodyTel™ to further promote their products and services, as Stefan Schraps, CEO of BodyTel™ stated:

The Continua certification will make GlucoTel™ compatible with a large number of telehealth systems from leading manufacturers. This especially benefits companies that are setting up a telehealth solution together with BodyTel™ – they rely on a safe standard and save both development effort and cost. In addition, our work in the consortium will help create future standards and lets us establish close relationships with industry peers.11

Thus, opening up parts of the technology, namely the interface to the company’s ecosystem, allows better cooperation and the establishment of new partnerships, as well as cost savings, while simultaneously benefiting customers and patients.
5. Organic Solar Cell Development for Clean Sustainable Energy

MINA MIRSAFAEI, EMAD YAGHMAEI

5.1. Executive Summary

Nanotechnology is one of the key elements of the worldwide societal challenge of ‘secure, clean, and efficient energy’. This challenge accounts for the needed transition towards an optimal and renewable use of energy resources and towards sustainable primary production and processing systems to produce energy with minimized inputs, environmental impact and greenhouse gas emissions, and with enhanced ecosystem services, zero waste and adequate societal value. The objective of our product is to contribute to securing sufficient supplies of clean and sustainable energy. It is fulfilled by developing productive, sustainable and resource-efficient production systems, fostering related ecosystem services, and the recovery of energy diversity, alongside competitive and low silicon supply chains.

The impact achieved by our work has been the development of an innovative organic solar cell based product, which has higher efficiency and longer lifespan. This sustainability aspect of the product is acceptable to users. There is a low level of toxic materials in both the clean sustainable production process and in the product.

To date, silicon based solar cell and thin film (such as cadmium-telluride, gallium-arsenide, etc.), representing the first and second generation of photovoltaic (PV) technologies, respectively form the majority of the commercial energy market. The applied photovoltaic technologies are mainly silicon-based and are expensive to compete effectively with fossil fuels for electricity production. In addition, silicon, cadmium, tellurium, gallium, and arsenic are environmentally demanding for recycling and disposal. Therefore, the environmental sustainability of these technologies is unclear.

To address these problems, the emerging organic photovoltaic technology offers large cost reductions using inexpensive materials and solution processing instead of expensive and slow vapor phase deposition, and provides the solution to this problem. The global interest in developing organic solar cells mainly stems from their potential to be flexible and stretchable, low cost, low weight, and semi-transparent.

The basis of the organic solar cell is the use of special organic compounds, donor and acceptor materials, which are sandwiched between two electrodes. One of the electrodes should be transparent which allows the light to penetrate into the device.

Figure 5 The schematic diagram of organic solar cell.
There are two major classes of organic solar cell: small molecule and polymer solar cell.

The schematic diagram of a typical polymer solar cell, which is used in this work is shown in figure 1.

Currently however, the low power conversion efficiencies of organic solar cells using the ceramic brittleness and high temperature vacuum deposition of transparent conductive oxides as a transparent conductive electrode, limit their viability and sustainability for cost competitive commercial production, and impede their application in flexible devices.

Transparent conductive electrodes (TCEs) are essential components in optoelectronic devices, such as organic light emitting diodes, and organic solar cells. Vacuum deposited indium thin oxide (ITO) film as TCEs have excellent physical properties, such as high optical transmittance and low sheet resistance. ITO films, however, have several drawbacks like fragility, a high refractive index and high processing temperature as well as large wastage of target material during the manufacturing process. Therefore, there is a strong need for alternative materials as TCEs in the next generation of optoelectronic devices. To date, various materials and nanostructures such as conducting polymer hybrid films, graphene, carbon nanotubes, metal mesh, and metal nanowires have been used as alternative to ITO films.

In this work, we developed a periodic ultrathin gold nanowire as an alternative nanostructure for ITO in organic solar cell devices, which give us both high transparency and low sheet resistance. In addition, the ability of tuning the optical properties of nanostructured metallic film, by varying shape, size and material, can enhance the light absorption in the organic active layer, and thus the efficiency of the device. Furthermore, the high electrical conductivity and mechanical elasticity of metallic nanostructures have been a major factor in advancing the application of this technique in a flexible organic solar cell.

### 5.2. Field of Industry or Service

The development of large-area ultrathin gold nanowires as a transparent electrode in organic solar cell falls under this case study. The periodic ultrathin gold nanowires are prepared from Langmuir-Blodgett films using a lithography method based on the self-assembly of polystyrene nano-spheres. This case study presents the light harvesting ability of periodic gold nanowires and the feasibility of integrating these inexpensive and easily scalable nanostructures into organic solar cells. The presented generic technique is compatible with up-scaling techniques and can easily be applied in various future optoelectronic devices in the energy sector.

### 5.3. Fabrication Methods

This work explains fundamental information about the periodic ultrathin gold nanowires fabrication method, including colloidal mask preparation via nano sphere lithography, mask modification and metal deposition. In addition, the fabrication of organic solar cells using ultrathin gold nanowires as a transparent flexible electrode, and the optical properties of ultrathin nanostructure in organic solar cells and their plasmonic properties are presented. Figure 2 briefly describes the fabrication process of periodic ultrathin gold nanowires.
5.3.1. Colloidal mask preparation

In this work a self-assembly of hexagonal closed-packed monolayer of polystyrene (PS) latex spheres in diameter of 1000 nm are used. Mono-dispersed polystyrene beads are purchased from Sigma Aldrich. The polystyrene solution with concentration of 2% in ethanol/water is prepared. The prepared solution is slowly applied on the water surface using a syringe. The monolayer of self-assembled PS spheres on the water surface is transferred on a clean piece of glass substrate and dried in air. Figure 3 shows the Langmuir-Blodgett set-up and the scanning electron microscope (SEM) image of the PS monolayer on the glass substrate.
5.3.2. Mask modification
One of the approaches to increase the spaces between the polystyrene (PS) spheres and open up the contact area between them is a reactive ion etching (RIE).

PS spheres are etched using 30 W power at a pressure of 150 mTorr, while etching ion-compositions include argon and oxygen. The amount of applied gases can vary depending on the size of the used spheres. Figure 4 shows the results of the etching of the PS sphere.

![Scanning electron microscope image of the polystyrene nanosphere after reactive ion etching.](image)

5.3.3. Material deposition
All evaporation processes were done using an e-beam evaporator. A 20 nm thick gold was evaporated at 10−7 mbar.

5.3.4. Mask lift off
After the metal evaporation on the substrate, the PS mask could be removed by lift-off treatment, based on ultra-sonication of the samples in acetone. The lift-off process takes from 30 seconds up to 1 hour depending on the film thickness and type of the structures. After the lift-off process the sample is rinsed several times with 2-propanol or acetone, then in Mill-Q water, and dried in a stream of Nitrogen. Figure 5 shows the ultrathin gold nanowires on glass substrate.

![SEM image of ultrathin gold nanowires on glass substrate.](image)
5.3.5. Organic solar cell fabrication
The device is realized on glass substrates containing ultrathin gold nanowires cleaned in an ultrasonic bath with acetone and isopropanol (10 minutes each step). The substrate is covered with poly (3,4-ethylenedioxythiophene) polystyrene sulfonate (PEDOT:PSS-PH1000) via spin coating at 400 rpm for 45 seconds. Subsequently, the 35 nm of nanoparticle Zinc oxide (ZnO) (purchased from Genes’Ink) is spin coated on PEDOT:PSS layer. Then, the blend of Poly[[4,8-bis[(2-ethylhexyl)oxy]benzo[1,2-b:4,5-b’]dithiophene-2,6-diyl][3-fluoro-2[(2ethylhexyl)carbonyl]thieno[3,4-b]thienenediyl]][6,6]-PhenyIC71 butyric acid methyl ester (PTB7:PC70BM) (1:1.5 weight ratio- purchased from 1-material: Solenne) dissolved in chlorobenzene and the 3%v/v of 1,8-diiodooctane (DIO), is used to form the active layer by spin-coating at 1000rpm for 120 seconds. The film is treated in a slight vacuum (10-1 mbar) for 20 minutes to accelerate the drying process and remove residual DIO from the thin film. Finally the 10 nm of Molybdenum three oxide (MoO₃) and 100 nm of silver are thermally evaporated at 10-7 mbar on top of the active layer.

5.4. Light harvesting ability of periodic gold nanowires
The absorption spectrum of the device with ultrathin gold nanowires shows broadband enhancement compared to the planar organic solar cells.

![Figure 6 Absorption spectrum of solar cell without gold nanowires (black curve) and solar cell with ultrathin gold nanowires (red curve). The light absorption within the device is enhanced by the factor of 6.6% (average in wavelengths) by integrating the gold nanowires in organic solar cells.]

5.5. Comparison to the other techniques
In our product, we used nanosphere lithography to produce the periodic nanostructures, which is a time–efficient and low–cost method in comparison to other lithographic techniques. The recent development of nanosphere lithography including etching the colloidal mask, using different materials and altering the metal evaporation angle on to the mask, gives us the freedom of producing nanostructures of various shapes. Furthermore, the ease to be adopted on various planar and curved surfaces, and the high throughput of this technique leads to a powerful nano-chemical patterning tool.

The mask design, their production, and scaling down the feature size usually remains as a challenge in conventional mask-assisted lithography techniques, however, nanosphere lithography embodies a self assembly of mono-dispersed nanospheres on a targeted
substrate, and the feature size can easily shrink below 100 nm by reducing the diameter of the nanospheres.

5.6. Events or Activity

Where conventional solar technologies cannot be used, OPV fills the gap. OPV technology benefits from the organic material properties and unlimited molecule designs and it can open up several opportunities for this particular market.

The transparency of the organic materials allows us to make semi-transparent photovoltaic devices, which can be applied in several applications such as greenhouses, urban furniture, anti-noise walls, bicycle parking and charging stations, shelters for train stations, and for outdoor and indoor decorations.

Using the solar panels to generate electricity decreases the cost of the powering, including the cost of cooling, heating and light. In addition, the ability to make organic solar cells flexible offers a variety of possibilities in terms of how they can be set up; on a tent, backpack, or rolled out on the ground.

Here are some examples for the application of organic solar cells.

(a) (b) (c) (d)

Figure 6 (a) Semi-transparent colored solar cell for urban application www.g2e.ch (b) Solar greenhouse on UC Santa Cruz campus www.universityofcalifornia.edu (c) The transparent version of Heliafilm integrated in the building’s architecture http://www.heliatek.com/en/applications/buildings (d) Flexible portable solar charger https://infinitypv.com
All advantages at a glance:

- Flexible
- Lightweight
- Thin
- Fast production
- Low cost custom design
- Cost efficient
- Green (no toxic or harmful materials)

5.7. Why does the case study fall under RRI?

OPV stands as a new technology approach; it is innovative and at the same time it leverages socially desirable mechanisms and is a sustainable energy solution. OPV offers decisive advantages including completely toxic-free manufacturing processes and low power need. A primary advantage of OPV technology over inorganic counterparts is its ability to be utilized in large areas, and flexible solar modules, specially facilitating roll-to-roll (R2R) production. Additionally, manufacturing costs can be reduced for organic solar cells due to their lower cost compared to silicon-based materials and the ease of device manufacturing.

The energy sector reacts by implementing such a sustainable and responsible practice from nanotechnology to grow its business more cleanly, to attract the best talent, and to remain relevant and sustainable to its inventors. OPV as a sustainable innovative product addresses RRI principles from two perspectives: process and product perspectives.

Conventional silicon cells require ultra-high-purity silicon — of the order of 99.999% pure — and the cells are made via energy-intensive crystal growth and vapour deposition methods. Further adding to their costs, "silicon solar cells use 1,000 times more light-absorbing material than dye-sensitized solar cells and perovskite cells," says photovoltaics pioneer Michael Grätzel, a chemistry professor at the Swiss Federal Institute of Technology, Lausanne.

OPV cells are made from an assortment of inexpensive materials, including organic polymers and small molecules. And unlike silicon cells, the emerging ones can be fabricated on flexible supports via inexpensive solution-phase techniques common in plastics manufacturing, such as high-speed roll-to-roll printing. Such development processes will reduce risks. In fact, the environmental risks and social issues of the inorganic solar cells are mitigated in OPV, so that its design process creates a competitive advantage by reflecting on the possible social impacts and aims of the product. Moreover, OPV’s production phase follows a sustainable value creation approach and has engaged different stakeholders into the design process. In principle, close integration and cooperation among engineers, researchers, and companies were required.

As such, since OPV production processes optimize environmental and social aspects in parallel to other strategic business priorities and manage financial, environmental, and social aspects across all strategic priorities, sustainability is understood as a driver of the long-term success of its business.

Accordingly, OPV helps to reduce production costs. Concerning a competitive advantage for such new business, companies and their founders can tap into new markets and remain relevant to a growing number of investors. The amount of money invested in OPV is growing...
every year through so-called SRI investment (socially responsible investors). And OPV provides an opportunity to launch new business models under the energy sector.

Altogether, the OPV production process is in line with the 2008 European Commission Code of conduct for nanotechnologies and follows the principles related to nanoscience and nanotechnologies. In fact, OPV respects fundamental rights, is safe, ethical and contributes to sustainable development serving the sustainability objectives, and does not harm or create a biological, physical or moral threat to people, animals, plants or the environment, at present or in the future.3, 5

5.8. The industry benefits (Successful application with Ultrathin nanowires - OPV)

An organic solar cell developed in this work can be combined with a great variety of materials, for example flexible substrate, concrete, etc. The flexible organic solar cells can also easily be integrated into concrete. In fact, the future of functional façade systems is the combination of flexible solar cells and concrete. The developed organic solar cell in this case study can be attached directly to the concrete façade without any need for cooling or ventilation systems. In all cases, organic solar cells reduce the operational costs, which helps companies in terms of sustainable purposes.

Organic photovoltaics are the most promising options for solar energy utilization and have some advantages, such as a fast manufacturing process, and the possibility to print and coat the device directly onto a flexible substrate by using roll-to-roll coating and printing methods which enables simple handling and low cost production.

In addition, the organic photovoltaic technology avoids the use of rare elements in limited supply, and the chemical synthesis of the organic material can be carried out completely irrespective of geography.

In the work presented above, we introduced an inexpensive and easily scalable alternative technique to replace the fragile ITO in organic solar cells. We used the nanosphere lithography method, which is low cost, and compatible with up-scaling techniques. Furthermore, we believe that this process can be applied for the flexible substrates and used in the flexible OPV technologies.

This technique can be easily developed commercially and address the problem of indium scarcity, as indium is the main component in ITO. In addition, it opens up new routes towards ITO-free electrodes in printed electronic devices.

5.9. References


5. Grätzel, M, *Recent advances in sensitized mesoscopic solar cells*, Accounts of chemical research, American Chemical Society, 42 (11), 1788-1798.
6.“On my own ... at work” – a framework and an app

Paola Vulterini

6.1. Executive Summary

The app of this case study has been designed within the framework of an Erasmus+ project\(^{57}\), funded by the European Commission, and promoted by the Associazione Italiana Persone Down (AIPD). Entitled “On my own ... at work”, the project is aimed at the inclusion of people with Down Syndrome (DS) and other intellectual disabilities (ID) as workers in the hospitality industry (www.on-my-own.eu).

Training on the job is the most effective method of training for a person with ID (Contardi 2016, Contardi 2004, Capie et al. 2006, Kamp and Lynch 2007, Lepri 2011, Lepri and Montobbio 2003, Williams 2011). During the training period, the trainee is assigned to an internal tutor (co-worker), who will teach the trainee about their work and introduce them to the work environment. Wherever possible a training agency introduces the trainee to the company and follows, through an external educator, the early stages of the placement. This involvement gradually decreases over time until it finally ceases. The external educator's role is to mediate relationships in the initial phase, and to foster the development of the trainee's own identity as a worker and their colleagues’ recognition of this. At the same time an external educator is identifying and suggesting educational strategies to the internal tutor and other colleagues.

The “On my own ... at work” app is intended to support the trainees during their traineeship, in order to gradually make them more independent of their tutors. However, it cannot and should not contain all the necessary information relevant to their job.

The app also helps tutors to organize the tasks to be assigned to the trainee. The main features of the app are as follows:

- The app has a flexible structure which has been developed according to the most frequently encountered difficulties faced by people with ID at work (Buzzelli et al. 2009, Job Accommodation Network 2013): time management, and retention of working tasks and tools. It is customised for each individual user.

- It is written in easy-to-read language.

- It uses pictures, videos and voice messages as much as possible.

The system facilitates the organisation of the working week, the working day, and work actions. This information is presented in the form of written text, pictures and videos. It also supports the retention of items necessary to carry out the assigned tasks. The tutor, together with the trainee, customises the content to the required needs and adapts it throughout the course of the training.

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\(^{57}\) Project number: 2014 – 1-IT01 – KA202 – 002642. AIPD’s partners: Associaçao Portuguesa de Portadores de Trissomia 21, Axis Hoteis Group, Down España, Fondazione Adecco per le pari opportunità, European Down Syndrome Association (EDSA), Alma Mater Studiorum University of Bologna, University of Roma TRE.
6.2. **Associazione Italiana Persone Down (AIPD)**

Associazione Italiana Persone Down (AIPD) is a national association of persons with Down Syndrome (DS) and their parents in Italy. Officially established in Rome in 1979, AIPD is a not-for-profit organisation and exists as a central point of reference for parents, professionals and anyone interested in Down Syndrome. The national headquarter is located in Rome, and 52 local branches are spread across Italy.

Its mission includes the following tasks:

- Supporting people with DS and their families.
- Promoting studies about DS and disseminating information.
- Supporting school mainstreaming, vocational training, job inclusion and independent living for people with DS.

### 6.2.1. Main AIPD activities focused on the target group (people with DS)

- Providing families, professionals and General Practitioner’s (GPs) with information and advice on all aspects of DS.
- Promoting and encouraging the full social and job inclusion of people with DS at a national level.
- Providing education / training services regarding independent living and vocational training locally.
- Disseminating information on DS to third parties.
- Informing GPs as fully as possible about DS through the publication of articles, pamphlets, folders, TV programs and the AIPD Down Syndrome Magazine and a library of reference texts.
- Promoting awareness-raising campaigns.

### 6.2.2. Main AIPD activities focused on innovation policy

- Promoting self-advocacy of people with DS.
- Promoting independent travel and meetings of people with DS throughout Italy and Europe (work experiences, youth exchanges, joint education projects).
- Promoting political rights through active citizenship and participation in political elections.

Since 2014, AIPD has held the chair of the European Down Syndrome Association (ESDA).

AIPD has previously promoted and coordinated three Socrates-Grundtvig projects, and a number of Youth for Europe and Youth in the World projects, in addition to a Europe for Citizens project.
6.2.3. Main AIPD activities in the area of job inclusion

AIPD’s Job Inclusion Office has the following aims:

- Raising society’s awareness of DS.
- Supporting job inclusion of people with DS.
- Keeping an up-to-date archive and library of data and laws relevant to DS.
- Liaising with bodies of public administration on matters related to DS.
- Authoring documents on job-related issues regarding DS.

The local branches set up and manage vocational training and job inclusion services, in cooperation with Local Public Authorities and Employment Offices. To date, 125 young adults (aged 18-30) with DS have been hired through these activities. The most recent example, well known across Italy due to its TV coverage, is the internship of six young people aged 18-31 with DS in a work environment. Its objective was to create a complete professional experience for them.

6.2.4. Previous European projects on job inclusion

Since 2007 AIPD has organised internships of Italian trainees with ID financed by Leonardo da Vinci IVT mobility projects in collaboration with In & Out Hostel, located in Barcelona.

Several Youth exchanges and Europe for Citizens projects existed. The main aim of these projects was to introduce people with DS to adulthood and raise European awareness of ID. A pedagogical approach based on meaningful activities, in which people with ID were integrated within a supportive environment, focused specifically on job inclusion, since working in a job constitutes an essential component of being an adult.

6.2.5. Previous national projects on job inclusion

AIPD coordinated “Lavoratori in corso” (2007), and “Il lavoro, i lavori” (2011), two projects about job inclusion of people with DS, financed by the Italian Ministry of Welfare.

6.3. Description of Field of Industry or Service

The app relates to at least three fields of industry / services.

- **Accommodation and food services industry.** The app has been designed to be used by people working in this sector, but it is planned to extend its implementation to other sectors by adding new job profiles. Up to now the app has been tested in large, small and medium sized enterprises like hotels, restaurants, bars, fast food outlets, B & Bs etc., according to the following training profiles:
  - assistant cook
  - chambermaid
  - café waiter
  - restaurant waiter
  - breakfast waiter
  - receptionist
  - beach attendant
  - spa receptionist
**Disability organisations involved.** Three different types of disability organisations can be distinguished:

- diagnostic-focused (such organisations represent a medical diagnostic group, for instance people living with DS).
- population-specific (these represent a particular group of the population, for example women with disability).
- cross-disability (these represent the interests of people with different kinds of disability).

Of these, three national population-specific associations of / for people with DS have implemented the field test of this app (in Italy, Spain and Portugal). Importantly, the app is also valuable more generally for people with other IDs.

**VET providers and placement services.** In addition to their own organisations, people with DS, and with general IDs, are supported by a number of Vocational Education and Training (VET) providers, according to the place they live at and the network they are able to build up. These can for example be mainstream schools or vocational training centres, as well as special or mainstream employment centres.

### 6.4. Description of the Product

#### 6.4.1. Our target group

According to the European Down Syndrome Association, Down Syndrome (DS) is the single most common cause of a learning disability and occurs at the rate of about 1 in 600 – 1000 births (i.e. 0.1-0.2%). The life expectancy of a person with Down Syndrome is currently approximately 60 to 65 years (European Down Syndrome Association, N.D.).

Access to work is crucial to ensure independent living and self-determination for people with ID, who face a much higher unemployment rate than the general population. The vast majority of people with ID have never experienced any form of vocational training, and this is a further hindrance to their access to the labour market.

According to US disability statistics (2015) only 26% of the labour force with ID is employed. For non-disabled people this ratio is 78% (Erickson et al. 2016). In the UK people with ID have the lowest employment rate (24%) among all those with other disabilities (Mirza-Davies and Brown 2016).

#### 6.4.2. The framework of the “On my own … at work” project for diversity

The app, aimed at facilitating work inclusion of people with ID, is just one of three tools provided by the project, “On my own … at work”. There is also a series of videos aimed at co-workers to illustrate examples of appropriate relationships between trainees with ID and their co-workers ([http://www.on-my-own.eu/en_GB/videos/](http://www.on-my-own.eu/en_GB/videos/)).
The third instrument is for the restaurant and hotel management wishing to join the network: a "**quality kit**", composed of a Code of Conduct, an application manual for the Code and a label that certifies their membership in the network.

The app, together with the other two tools, can be adopted as a whole or separately, according to the specific situation of an organisation or company. It represents a tool aimed at diversity management.

**6.4.3. Why did we design the app? Which needs did we address?**

The idea of the app arose within AIPD after many years of experience with vocational training and job inclusion of people with ID.

By definition, in a process of "training on the job" there is no difference between practice and theory and the main learning feature is "learning by doing". The textbooks' of a chambermaid, for instance, are usually trolleys of detergents and bed sheets.

It has been observed (Sampaolo and Danesi 1993) that the recurrent difficulties of a person with ID in a work context are often linked to the organisation of their work and to memorising the assigned tasks. The usual solution to these difficulties is the continuous or reiterated presence of a tutor. Such a remedy risks damaging the autonomy of the worker / trainee with ID who becomes dependent, but it also consumes the time of their colleague. Sometimes specific check lists of the duties that have to be performed are provided. However, these check lists need to be revised continuously, which is time consuming.

It must also be taken into consideration that some tasks, for instance the way to set a table, may be misunderstood, if the explanation is just made orally. The visual description of a real or virtual model is very effective in these cases (Reynolds et al. N.D., U.S. Equal Employment Opportunity Commission N.D.).

Greater autonomy and the need for a renewable and visual model of the duties assigned are the main reasons why the interactive app was developed. "On my own ... at work", is usable on a smartphone or mini tablet, which can be carried in the pockets of the trainee / worker.
6.4.4. The app: how is it structured?

The system is structured on three levels:

- **Super admin** (managed by AIPD): enable / disable tutors; view all content; register tutors and users.

- **Admin** (managed by tutors): enable / disable users; manage and customise users’ profiles; edit and post content; use the archive.

- **User** (trainees/workers with ID): download and login; customised view: work role; daily planner and weekly schedule.

It provides the following functionality:

- The organisation of:
  - the working week,
  - the working day, and
  - actions to be carried out to accomplish a single task using checklists.

  This is presented in the form of written text, pictures and videos.

- The retention of items or equipment necessary to carry out a particular task.

The tutor, together with the trainee, customises the content, which is stored in three folders:

- **User** (trainee profile and organisation of week and day)

- **Contents** (tasks and checklist)

- **Tools** (items and equipment)

Each trainee's app can change throughout the course of the training, by adding or removing content.

Use of the app may be reduced or abandoned over time with the achievement of autonomy in the tasks. Alternatively, it may be continued once a trainee is formally employed as a way of continuous support for workers with ID.
6.5. Product Development, End-User Engagement Activity and Diversity Issues

6.5.1. Product development

Three nationwide Down Syndrome associations, from Spain, Portugal and Italy, designed the app in line with the results of an observation period, and two subsequent testing periods. End-users were involved from the start. They acted as testers during the observation period and collaborated actively with tutors to customise the app with appropriate resources. At the end of the extended testing period all participating trainees will complete an easy-to-read evaluation questionnaire.

The app was developed starting from field-action research. The field work was implemented according to a jointly agreed research protocol. The first step was a preparation and observation period in Portugal and Italy (November 2014 – April 2015) in order to identify the training needs.

The period from November 2014 to February 2015 was devoted to background research, designing the observation protocol and selecting trainees for the study.

Based on the results the following criteria were adopted to select trainees with DS to take part in the project:

- basic calculation and writing / reading skills
- independent living skills
- physical and social skills
- previous experience of internship (if any)

Seven young adults with DS were then engaged by the hotel sector as trainees. Educational researchers recorded, using specialised observation protocols, the following issues:

- the trainees’ difficult moments
- the tools adopted
- critical situations
- strategies found both by the person and by the hotel tutor during the execution of assigned tasks

The trainees were observed continuously during this period and observation forms were completed weekly by the researchers assigned to this task (March-April 2015).

6.5.2. Areas of observation

The tasks that were recorded during the observation phase were:

- arrival at work / compliance with schedules / timetables
- planning and scheduling the tasks
- carrying out the tasks
- specific tasks undertaken (related to the work situation)
- flexibility and adaptation with respect to a specific task / work situation
- interpersonal relationships
Based on the findings from this observation period the app was designed and produced during April – September 2015.

The third step was the customisation of the app to each trainee, job position and company, by the tutors together with the trainees. This was undertaken during the first testing period (October 2015 – April 2016). Twenty-four trainees with DS in Portugal and Italy took part in this testing phase.

6.5.3. A summary of the evaluation of the app by the tutors

The general opinion of Italian and Portuguese tutors was that the app is a valuable instrument for the trainees. “It’s useful and really helps trainees to do their job.” (Feedback from one of the Italian tutors).

Most of the trainees used the app daily as an effective assistive tool and became autonomous in their tasks. It also helped with their motivation and the relationship with their tutors, which proved to be very important for effecting positive results.

Although the app is easy to understand, it takes time to learn how to use it, to handle it independently and to customise it. Most of the trainees were very motivated to use the app as using a tablet or a smartphone at work was seen as an important responsibility and as a factor supporting inclusion.

The following sections provide further results from the initial evaluation.

6.5.4. Careful design and planning work

The app requires time for creating profiles, uploading photos and videos, designing checklists, designing and planning an overall objective and transforming it into a simple concept that can be implemented in the app. All these tasks have to be planned and the design has to be adjusted carefully to make best use of this resource.

6.5.5. Customisation of the app by a disability expert

It is important that the design part is undertaken by a person who has experience with people with IDs, because it is not easy to decide what the trainee has to do, in which way, and which content is important to insert from the start and which can be added later. The app is particularly useful in the initial stage of an internship and after some months it becomes a familiar instrument of self-monitoring. This depends also on how much the host company is prepared to support the trainee with ID, and how much it wants to foster the possibility to teach them new tasks.

6.5.6. The app is not suitable for everyone

Some crucial factors that influenced the suitability of the app included:

- degree of autonomy
- type of job
- relationship that colleagues have with the trainee

6.5.7. The app: how the trainees used it

The tutors reported on a range of interactions with the app by the trainees and the different factors that influenced their experience.
6.5.8. Familiarity with apps and technological devices in general
Not all trainees were familiar with smartphones and apps; this fact influenced the results.

The app was either uploaded on trainees’ smartphones or onto a tablet device. At the start of
the project the app was only available for Android devices, which caused problems for some
of the trainees.

It took a considerable length of time for some trainees to learn how to use a tablet device and
this required a lot of their working time; some others did not like smartphones and were not
interested in using a new device.

6.5.9. Interest in the app
All trainees seemed to be satisfied when using the app, and certainly at the beginning they
were all very enthusiastic.

By the analysis of this phase we saw that if the tutors showed a high motivation (i.e. they
believed in the effectiveness of the instrument and were willing to support it), trainees were
also highly motivated. Clearly, this is an important factor for the management of the trainees
and of the tool.

As the trainees became more familiar with the tasks assigned, the app became less
necessary; it had served its purpose. This gradual growth of the trainees’ independence was
a welcome outcome. It can be said that the app was designed to make itself superfluous.

6.5.10. Usefulness
In general, trainees understood the instructions well, and how to handle the app. This tool
helped them with their job, mostly for remembering tasks to do.

Most trainees thought that checklists were the best content of the app because they helped
them to organise their work.

Images were very important for the visual control of some tasks to be performed (e.g. how to
prepare the table).

The utility of the app depended on the individual situation of each trainee and their work
position: if the trainee was already autonomous and the tasks were simple and repetitive, then
the app might not have represented additional help.

6.5.11. Distraction and external issues
Not all trainees understood that the app could be a help in their job; sometimes it was seen
more as a game than an assistive tool. The professional tutor needed to present the tool in an
effective way to make this clear from the start.

In some cases the app proved to be a distraction (especially if it was uploaded on the
smartphone of trainees).

In some work places poor Internet connection proved to be a problem. Some trainees had to
walk around the hotel searching for Internet signals, and this took out time from work.

6.5.12. App ‘moments’
Usually trainees used the app at the beginning of a task or during their breaks. Generally
trainees used it on their own, but sometimes the use of the app was not automatic and it was
necessary to remind them, mostly in the first part of their training.
Not all trainees used the app often. The main reasons for this included:

- Effective working time: sometimes trainees did not have time to stop and get access to the app.

- Some of the tasks performed by trainees required manipulation of water, oil or wet fabric, which made the simultaneous handling of the tablet device difficult. In such cases, while it was not helpful for the execution of the tasks, it was still important for self-monitoring.

Currently (October 2016 – May 2017) the “extended testing” of the app (and videos, see above) is under way in Portugal, Spain and Italy. In total 59 trainees and 41 hotels, restaurants and catering services are interested, or have applied for the label associated with this programme (see above).

6.5.13. A supplement of dignity

Many employers are willing to recruit people with ID, even if this means that tasks may take longer to accomplish. However, they cannot “waste” another resource (i.e. tutor) just to follow the worker with ID. The increasing independence of the trainees with ID from their tutors - as facilitated by the use of the app - means that a company can manage the inclusion of people with ID with reduced human resources. For some users the app also led to a profound learning experience and allowed them to be able to undertake the assigned tasks eventually without the app and only with infrequent input from their tutor.

This tool also leads to greater dignity through self-reliance of people with ID, as they can manage their assigned tasks on their own, on equal terms with their work colleagues.

6.6. Why the “On my own ... at work” app is relevant for RRI

6.6.1. Social justice / inclusion

“On my own ... at work” fits this RRI criterion, notably “access to education, labour market inclusion and non-discrimination”. The app allows trainees and workers with ID to become more independent and to integrate better into the organisations they work in. The app supports them in realising their access to work.

Furthermore, the app is accessible to a wide variety of social groups; all those who need easily comprehensible texts: people who are illiterate or with low education, or migrants. It is free.

6.6.2. Science education

Trainees with ID have tested the app during the pilot test period. They were considered as RRI actors and contributed to the development of the app, which is being used by other trainees with ID, who will thereby also be motivated to use ICT.

6.6.3. Open access

Open access is provided to the development process of the app with updates on the website and a blog of the project. The extended testing has involved many organisations which were not official partners of the project, in order to share ideas and comments before the final

58 http://easy-to-read.eu/
release of the app. Organisations who intend to use the app (VET providers and hospitality companies) can apply to AIPD and a protocol is signed. The app can then be pre-filled with personalised data and useful resources for the individual trainees.

6.6.4. Rights
RRI must respect fundamental rights and should adhere to the highest ethical standards. The app has been designed in order to support the right to work of the 0.1-0.2% of the European population with ID, and to increase inclusion, as requested by the UN Convention for the Rights of People with Disabilities (CRPD) (UN Division for Social Policy and Development Disability 2006).

6.7. Potential Benefits ... Not Only for Key Players
The app is of use for distinct groups of stakeholders - people with disabilities, disability organisations, and the hospitality sector. It is an example of responsible innovation where the potential benefits reach targeted players, both separately and jointly.

Benefits for people with intellectual disabilities.
- Potential for a lower unemployment rate.
- Enhanced autonomy thanks to the opportunity to use an electronic advisor and organise their job on their own.

Benefits for VET providers.
- Higher placement rate with lower resources, since the app, together with the other two tools of this project (see above), facilitates inclusion and requires less person hours than in the past.
- Long-lasting partnerships with hospitality businesses.

Benefits for disability organisations.
- Higher levels of social inclusion for their members.
- Long-lasting partnerships with hospitality businesses.

Benefits for the accommodation and catering services industry.
- Easier compliance with the quota system (compulsory percentage of workers with disabilities out of the total number of employees) in countries where this is mandated.
- Greater diversity in their workforce.
- Easier inclusion process for SMEs, due to a reduced need to dedicate human resources to assist trainees with intellectual disabilities.
- Long-lasting partnerships with VET providers and with disability related organisations, which can support the inclusion process, but also provide the company with an insightful view of the needs of potential clients with ID.
Benefits for **society in general**.

- Potential for a lower unemployment rate for people with ID.
- Potential for a group of citizens to become less reliant on social security assistance, but to attain a degree of independence and to contribute to the payment of taxes.

### 6.8. References


Capie, Angus; Contardi Anna and Doehring, Diane (2006) *Transition to Employment. Down Syndrome Educational Trust*


7. Appendix Case Study
Competition

Call for Case Study on Diversity

Join the competition!

Responsible Research and Innovation and Diversity
We invite the submission of success story case studies on responsible research and innovation in industry with a focus on diversity issues. The winning case study will be used to develop an interactive online platform, the Responsible Innovation Compass and serve as an inspiration to companies. By “diversity”, we refer to a diverse work force, e.g. a work force with good gender balance or the representation of minorities (e.g. ethnicity).

Win EUR 3,000 for your inspiring case study!

The competition is open for three key innovation fields: Healthcare, Nanotechnology and ICT (ICT innovations are also eligible). There are no restrictions on geographic location, or type and size of company. The case studies can be from any organisation or background (e.g. industry, academia, policy making, civil society organisation). Small and Medium-Sized Enterprises are particularly invited to apply!

(View examples of winning case studies in an earlier, similar competition here: http://www.responsible-industry.eu/activities/bu-casestudies-results)

https://innovation-compass.eu/cases/

**Competition Deadlines**

Submit your responsible innovation success story in nanotechnology or healthcare!

- Submission of abstract: 28/02/2017
- Selection of winners: 15/03/2017
- Full case study deadline 15/04/2017
Competition process

How to apply

To streamline the application process, the case study competition will have two phases, (Phase 1 requires minimum input).

Phase 1

We invite you to submit an abstract of your responsible innovation case study (max. 1,000 words) in English, including

1. an abstract of the case study (max. 500 words)
2. an explanation of why the case study is important in the context of diversity (max. 300 words, for instance, are gender equality/diversity/diversity management strategies or measures implemented, such as programs on equal opportunity, supplier diversity, equal pay initiatives, diversity trainings, diversity related recruiting processes and human resources development, diversity-sensitive product and service development, etc.)
3. an explanation of why the case study is relevant for Responsible Research and Innovation (max. 200 words, for instance, how does it align with the RRI action criteria published by the European Commission’s Science with and for Society Unit?)

All intellectual property rights in the case study will remain with the authors. Please email your case study to Prof. Doris Schroeder: dschroeder@uclan.ac.uk. Prof. Schroeder is also available for questions.

Is your case study eligible?

Tells a success story about responsible research and innovation based on a diverse workforce or with excellent management of diversity issues
Describes innovative products, services, designs, business models or social innovations which explicitly consider diversity issues, such as age diversity, gender diversity or ethnic diversity.
Must be based on real experiences and events
Must be original, i.e. unpublished in this or a similar form, and not older than 5 years
Must fall into one of the two sectors: healthcare or nanotechnology (ICT in healthcare and nanotechnology is also eligible)
No personal data must be revealed in the case study, unless the consent of the relevant person has been obtained
No direct or indirect connection to the COMPASS project is allowed to avoid a conflict of interest in the selection (members of other RRI projects and their associates are eligible to apply)

If you are not sure if your case study qualifies, please consult Prof. Doris Schroeder at dschroeder@uclan.ac.uk.
Phase 2

After a panel of experts from the COMPASS project have reviewed the submissions, the author of one shortlisted case study will be informed on 15 March 2017 and will have one month to set out their case study (deadline 15 April 2017) and submit a full description (no more than 10 pages) according to the following headings:

1. One page Executive Summary
2. Description of field of Industry or Service
3. Description of activity and gender equality and/or diversity issues (product or service development, end-user engagement activity etc.)
4. Description of the benefits for industry.

The submission must be in English and no longer than 10 pages.

The selected case study will benefit from being showcased via the COMPASS website and may be used – with the authors’ consent – in publications or other dissemination materials and activities.

The winner will be informed by 15 March 2017 and invited to submit the full case study.

Selection criteria

- Relevance of the case study to the field of RRI
- Explicit reference to gender equality/diversity issues, strategies and measures
- Fit to industry sectors: healthcare, nanotechnology or ICT
- Originality of the issues addressed
- Transferability and relevance to other applications, technologies etc.
- Engaging writing style

Criteria are all weighed equally and will benefit from quality assurance through peer reviewers. Authors will be requested, if necessary, to make changes based on the peer review. Only upon final acceptance of the case study, will the prize money be released.
About COMPASS

The COMPASS project is one of a range of EU-funded projects focusing on the idea of “Responsible Research and Innovation” (RRI).

Responsible Research & Innovation (RRI) is:

- Involving society in science and innovation ‘very upstream’ in the processes of research and innovation to align its outcomes with the values and needs of society.
- A wide umbrella connecting different aspects of the relationship between research and innovation and society: gender equality and diversity, ethics, science education, governance, public engagement and open access.
- A cross-cutting issue in Horizon 2020, the EU programme for Research and Innovation 2014-2020.

The project investigates whether RRI can improve research, development and innovation in industry. Possible improvements are being investigated both in terms of processes and in terms of positive outcomes for industry and society.

The main output of the project is an interactive online platform, the Responsible Innovation Compass, which will provide guidance and orientation on RRI implementation tailored towards the needs of innovative enterprises, in particular SMEs. To contribute to our research, a bottom-up call for case studies of successful examples of RRI is integrated into the project.

Learn more about what COMPASS can bring to your business

- Gain visibility for your success story through our case study competition
- Participate in Responsible Innovation Labs
- Get expert support for implementing responsible innovation in your business

Find out more at

www.innovation-compass.eu