

Responsible Innovation Roadmap

Biomedicine

Step 1: Embed vital and review desirable aspects for company management.

Step 2: Reflect on integration of responsible innovation practices throughout the entire innovation process of your company.

COMPANY MANAGEMENT

Vital

- ❑ Developing, reviewing or re-affirming mission statement to set context for responsible innovation that can include new service frameworks – to meet the health needs of people.
- ❑ Ensuring commitment to ethical and safe modes of operation for products and services at stages of (a) research; (b) design and preparation; (c) production; (d) marketing and sales; (a) idea generation and research; (b) design, development and testing; (c) production, (d) marketing and sales, and (e) purchase and usage in both healthcare and home settings (as applicable).
- ❑ Recognising the importance of data security (in the context of the GDPR) and the particular regard that needs to be taken for (safeguarding of) health data.
- ❑ Demonstrating readiness to engage with and respond to feedback from customers, end users (patients), and other stakeholders, and involving them in decision-making processes.
- ❑ Demonstrating a commitment to interoperability (technical, organisational and legal) for technologies and communications that relate to health (in both clinical and preventative contexts).
- ❑ Adhering to codes of practice and applicable standards, and obtaining certification after compliance established via an accredited external agency.
- ❑ Working and collaborating with a relevant industry association body with a shared ethos and, with or independently of it, to contribute to standards development in the field.
- ❑ Continuing adherence to the crucial values around care (and ‘doing no harm’) but seeing this in a new context of digital health that includes e.g. wearable and implanted devices, robotics and AI.

Desirable

- ❑ Being forward in raising public awareness of issues for health technologies and, in particular, their potential for empowering consumers and service users.

IDEA GENERATION & RESEARCH

- ⇒ Base research on the best evidence available and be ready to consider implications of new knowledge arising from ongoing research.
- ⇒ Give specific attention to research that relates to user perspectives and the need for their greater empowerment and choice; include attention to risk avoidance (including through cyber-breaches).
- ⇒ Be sure about market need for the product and that the technologies or services are appropriate to meet that need.
- ⇒ Reach out to and use feedback from stakeholders (including users) to inform the research.
- ⇒ Be very aware of emerging standards and be ready to conform with requirements that may relate to these.

External Engagement

Regular feedback from clients, customers and users - impacting on design and production.

DEVELOPMENT & TESTING

- ⇒ Ensure 'Safe by Design' approach embedded in all stages.
- ⇒ Utilise designs or product configurations that are suitable for the context in which they will be used.
- ⇒ Recognise the need for product 'fit' in relation to specific standards.
- ⇒ Involve users at key stages to assist in the design of products or services.
- ⇒ Ensure regular feedback and discussion with designers and researchers regarding matters arising during the production process (or preparation for the same).

Internal Feedback

Regular feedback within the organisation

MARKET & IMPACT

- ⇒ Provide clear and comprehensive information about the product in all marketing activities (including risks).
- ⇒ Use terminology that does not stigmatise or prey on fear. Recognise that users (and patients) respond best to products and services that offer choice and empower.
- ⇒ Guide, with absolute clarity, users regarding the use of products and services.
- ⇒ Maintain contact with users over a sustained period in order to ensure effective use and gather relevant feedback.

How to read this roadmap:

- ☐ Solid lines represent transitions between stages.
- ☐ Dotted lines represent feedback.

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