IHI Call Days | Call 9

Manufacturing Innovation in Complex Therapies Through Decentralised and Automated Networks

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Challenges and objectives

- Describe concisely how your proposal will address the challenge(s) of the IHI JU's specific objective of your choice (as described in the **IHI Strategic Research and Innovation Agenda**)

  - What problem(s) are you trying to solve
    - Cyber-crime and attack cost the global economy $10.5 trillion and on average cost $4.8M per event in the pharmaceutical and healthcare sector. The highest of any sector. This represents a significant threat when intending to decentralise the manufacturing-supply chain and stands in the way of creating a more interconnected, integrated healthcare delivery network. i.e. without effective secure models of what good looks like, the financial uncertainty of decentralising the manufacturing/healthcare network will be too great for investors and will hamper progress.
  - Which IHI specific objective(s) are you addressing?
    - **Objective 2** - Integrate fragmented health research and innovation efforts by bringing together health industry sectors and other stakeholders. This will enable the development of tools, data, platforms, technologies and processes that will in turn facilitate the prevention, diagnosis, treatment and management of diseases, especially in areas where there is an unmet public health needs.
    - **Objective 3** Demonstrate the feasibility of people centred, integrated healthcare solutions.
    - **Objective 4** - Exploit the full potential of digitalisation and data exchange in healthcare
  - Which unmet public health need are you addressing?
    - Automated 3-D Bioprinting and mRNA production could be brought into a 'direct-to-patient' and 'point-of-care' supply paradigm if secure networks were created (enabling choice and better health outcomes), but in the absence of security concerns being allayed the risk of attack outweighs the benefit of the network from a payer perspective.
    - At present there are few cyber security demonstrators as it is difficult to openly demonstrate security measures and remain secure. There are appropriate standards in existence (NIST and IEC 62443 for example) for manufacturing (OT) and IT, but there is not a standard by which these worlds are brought together as teaching-demonstrators.
    - Creating cyber secure manufacturing demonstrators would enable robust networks to be invested in, creating more choice and better healthcare outcomes for patients.

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Your approach to solve the problem

- Why is your proposal a good fit for IHI? IHI aims to fund large-scale projects focusing on health innovation. Explain:
  - Where do you see the contribution of industry in your proposal?
    - Industry would engage in automation of the manufacturing acts (Pharma), as well as the deployment of current best practices and tools for cyber security (Tech). This would be from both a technical perspective (how to build robust networks) and from a financial risk-assessment perspective (how to assess if it is secure enough).
  - Why do you require different health industry sectors (e.g., pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging heath ICT)?
    - How to robustly secure the manufacturing supply chain against cyber attack when decentralising control is a significant problem for all stated industries. We would target the pharma and vaccines space in the first instance, but would roll out the risk tools developed to the other industries.
  - Why does your project proposal require collaboration between private (industry) and public partners (e.g., academia, healthcare practitioners, patients, regulators)?
    - The proposal requires collaboration as no single entity has the answers. Academia know about the problems and solutions, but lack the scale to meet industrial need, industry lack the ability to demonstrate without creating alternative cyber-risks. Regulators need to be assured that changes in modes of supply won't compromise quality to patients (and that is not possible in hacked systems). Patients and practitioners need to have better access to novel therapies. All of these outcomes require better understanding of the risk (and means of mitigating it) of cyber security through demonstration of how to be secure.

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Is your project suitable for IHI?

- IHI aims to fund large-scale projects focusing on health innovation. Explain why a public private collaboration is essential to develop your proposal
  - The proposal requires collaboration as no single entity has the answers. Academia know about the problems and solutions, but lack the scale to meet industrial need, industry lack the ability to demonstrate without creating alternative cyber-risks. Regulators need to be assured that changes in modes of supply won't compromise quality to patients (and that is not possible in hacked systems). Patients and practitioners need to have better access to novel therapies. All of these outcomes require better understanding of the risk (and means of mitigating it) of cyber security through demonstration of how to be secure.
- Where do you see the contribution of industry in your proposal? Why do you require different health industry sectors (e.g. pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)?
  - How to robustly secure the manufacturing supply chain against cyber attack when decentralising control is a significant problem for all stated industries. We would target the pharma and vaccines space in the first instance, but would roll out the risk tools developed to the other industries

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Outcomes and Impact

- Short term
  - Companies adopting design (automation and network designs) and investing in de-centralised supply chains.

- Medium term:
  - Commercial companies trialling more medicines in the EU.
  - More mRNA and 3D bioprinted products on the market.
  - New Cyber security standards implemented

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Expertise and resources

- We have:
  - OT cyber security best practice demonstrator for decentralised real time release (single production technology, single-site so unable to demonstrate across a network).
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  - Automation team, data science team, GMP quality team.
  - Links into Industry (pharma and tech). Links to NHS as healthcare provider.
  - Links to mRNA academics and producers.
  - GMP license in mRNA production.
- We are looking for:
  - Cyber security (IT)- cloud and on-premises methodologies.
  - OT cyber security best practice demonstrator for decentralised real time release (single production technology, single-site so unable to demonstrate across a network).
  - Threat detection expertise.
  - Financial risk assessment expertise.
  - 3D bioprinting (as a manufacturing technology)

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