IHI Call Days | Call 9

Get Medicines to Patients

Contact person name: Jim McGuire, Sean Ruane
Organisation: Centre for Process Innovation
E-mail: jim.mcguire@uk-cpi.com; sean.ruane@uk-cpi.com

innovative health initiative

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**
    - The aim is to transform patient treatment by enabling the safe development of innovative, personalised products such as cell or gene therapy that need to be manufactured close to the individual patient or drugs with short shelf-life that need to be manufactured and delivered to patients rapidly, including digital systems enabling remote real-time monitoring of drug delivery and clinical response using advances in medical devices and in-vitro diagnostics.
    - The approach will help relieve pressures on hospitals by enabling delivery of care where it is most appropriate for the patient, in community settings (hubs) or even in their homes, supporting the ambition to expand 'hospital at home' services such as virtual wards.
  - **Which IHI specific objective(s) are you addressing?**
    - (SO4): Exploit the full potential of digitalisation and data exchange in healthcare. Making better use of opportunities to gather health data and use it in research and care, all while respecting relevant privacy legislation.
  - **Which unmet public health need are you addressing?**
    - With a rising requirement for personalised medicine to improve patient outcomes, current digital systems, manufacturing, quality control, distribution and regulatory functions are at risk of becoming an even greater bottleneck, preventing transformation to more cost-effective and health-effective medicines. This proposal will progress solutions to enable this delivery.
    - Just-In-Time (JIT) ordering is required to enable healthcare providers to request the manufacture and packaging of specific medicines on demand, directly connecting to the supply chain and enabling decentralised delivery and monitoring of medicines/trials.
    - Real-Time-Release (RTR) of medicines, reducing the held inventory awaiting testing and subsequent costs and delays. The agile and integrated technology approaches in this proposal will allow monitoring, planning, and forecasting to ensure optimal management of drug supply, especially for personalised or distributed manufacturing.
    - Integrated and connected technologies, will ensure end-to-end digital connectivity, communication, data analytics and processing, utilising cloud capabilities and AI to maximise efficiencies and identify risks.

innovative health initiative

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:
  - Project GM2P will develop:
    - A digital framework for Just-In-Time ordering.
    - A digital framework and infrastructure development for real-time-release, delivery and monitoring of medicines.
  - These frameworks will be tested in at least five key use cases to demonstrate their wide-ranging applicability and require collaboration between private and public partners:
    - Pharmacy Automation for Clinical Efficiency: This prototype packaging and labelling system will be used to develop the necessary digital integrations.
    - UK Continuous 2 Antibody Production Line: This use case will focus on large-molecule drugs, where JIT and RTR capabilities lag significantly. GM2P will integrate and demonstrate the required technologies into an existing digitally-enabled production process.
    - Remote Drug delivery solutions: e.g. Microneedles, inhalables, patches, responsive technologies that can connect digitally as part of the end-to-end solution.
    - Remote Drug Distribution: Drone supply with mitigation support vehicles – digital real time monitoring, ensuring product/data integrity and security.
    - Remote Patient Monitoring: wearables, in-vitro diagnostics - responsive technologies that can connect digitally as part of the end-to-end solution.

innovative health initiative

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
  - Addressing these challenges requires collaboration across the pharmaceutical industry, healthcare providers, and regulators to enhance infrastructure without creating new bottlenecks.
  - GM2P will require collaboration with public partners for regulatory release, patient compliance and experience, and ensuring accurate ordering, manufacturing, and delivery for healthcare practitioners.
  - Ensuring their quality, safety and efficacy, with the consequent benefits both to patients and the healthcare system is critical.
- 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)?
  - Private partners bring essential manufacturing capabilities, knowledge and technology development, while academia contributes pre-competitive innovation. Research and technology organizations (RTOs) will provide coordination, expertise, and a neutral platform for collaboration. As a wide range of technologies can benefit healthcare delivery, it is imperative that the different industry sectors responsible come together to overcome barriers to adoption.

innovative health initiative

Outcomes and Impact

- Significant development towards JIT ordering, including a demonstrator system and an open framework to enable wider adoption.
- Improved RTR functionality for small molecule drugs, with a regulatory portal for accessing data. Progressing RTR for large molecule drugs, with a demonstrator system illustrating technology potential for other formulations.
- Collaboration across the pharmaceutical industry, supply chain, healthcare providers and regulators will ensure translation into healthcare ecosystem.
- The proposal widens opportunities for clinical development of more therapeutic solutions, increasing efficiencies and competitiveness of health industry and improving patient outcomes.
- Project will deliver impact by accelerating release of medicines to patients. Digitally connecting the supply chain, real-time monitoring, analysis and reporting of the available data enabling patient-centric approach.
- Enabling new and innovative ways of provision of medicines closer to the patients who need them whilst ensuring quality, safety and efficacy, benefiting patients and reducing burden on healthcare systems.

innovative health initiative

Expertise and resources

- We have:
  - CPI has proven experience building and organizing large cross-industry consortia.
  - MMIC expertise for Grand Challenges, including PACE (GC2) demonstrates track record of delivering and coordinating large complex multidisciplinary projects involving automation and digital infrastructure in dynamic environments.
  - Healthtech, Medtech, Formulation, Photonics expertise.
  - Continuous biologics production and PAT integration at development scale.
  - Strong experience in working with regulators to develop collaborative solutions.
  - Close links with healthcare and academic institutions to develop DCT Direct to patient/site approach and drone expertise partners including logistics.
- We are looking for:
  - Biologics PAT and analytics partners to develop in/on-line quality measurements.
  - Pharmaceutical Partners to inform suitability for a variety of real-world processes.
  - Regulatory partners
  - Drug delivery technology partners
  - Diagnostic monitoring solution partners
  - Digital, AI and cloud partners to develop and advance infrastructure.

innovative health initiative