

IHI Call Days | Call 9

- Personalisation and Stratification of Healthcare Solutions

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Challenges and Objectives

- **Challenge:** Individuals are currently treated with a universal dosage of a pharmaceutical product that can potentially be non-specific and non-targeted. Factors such as age, gender, weight and genetic variation can cause individuals to respond differently to such treatments, potentially even rendering them ineffective or leading to unwanted side effects.
- **Addresses SO3:** Demonstrate the feasibility of people-centred, integrated healthcare solutions
- **Solution:** This proposal is to create a common framework for personalised medicine whereby the development, manufacture and regulation of pharmaceutical products can be designed to maximise the therapeutic benefit to the individual patients.

Approach to solve the problem

Activities will include:

- Review of current ways of working in terms of process development, manufacturing and clinical trials
- Adaptation of process development pipelines and manufacturing to enable personalised treatment in a sustainable manner
- Definition of clinical trials with regulators to establish efficacious dose ranges for pharmaceutical products to account for individual traits
- Development of systems/ tools for end user to prescribe medication in the clinic
- Look at economic/ reimbursement models
- Review of process across the international network to work towards common adaption of processes with industry and regulatory bodies

- **Anticipated project duration: 5 years (minimum)**

Is your project suitable for IHI?

- **Need for Public-Private Collaboration:** Delivery of this proposal would require a multi-disciplinary team from across the healthcare ecosystem. The aim of this proposal would require expertise across public and private entities to ensure common adoption of our proposed approach internationally.
- **Industry Contribution:** Input will be required from pharmaceutical partners to help create a common framework for personalised medicine whereby the development, manufacture and regulation of pharmaceutical products can be designed to maximise the therapeutic benefit to the individual patients.

Outcomes and Impact

- **Results/outcomes and impact?**

- The impact of this proposal would be to deliver an improved and efficient healthcare system to personalise treatment that maximises the therapeutical benefit of pharmaceutical products.
- Outcomes of the proposal would be to build frameworks across the whole operation from manufacturing through to administration
- Stratification of treatment options bases on individuals
- More environmentally sustainable healthcare through reduced consumption and waste of pharmaceutical materials
- Design and delivery of efficient clinical trials to enable flexibility in dosages across the population for personalised treatment
- Establishing dosing models and appropriate systems/tools for administration in the clinic
- Reimbursement models for treatments and more effective healthcare spend

- **Translation**

- This proposal aims to build on the current healthcare ecosystem and infrastructure that is in in place for the manufacture, testing and administration of pharmaceutical products which will aid in the adoption of personalised treatment within this ecosystem.

- ***Increasing competitiveness of the Union's health industry***

- Delivery of innovative healthcare across international framework - potentially enabling continued innovation in the future across different modalities
- Creating optimal treatments for individual that maximises the therapeutical potential of pharmaceutical products
- Reduced waste and more effective healthcare spending
- Design and delivery of efficient clinical trials to aid personalised treatment

- ***Benefits for patients?***

- By overcoming challenges associated with ineffective treatments and maximising the therapeutical benefit of pharmaceutical products, individuals can experience improved quality of life, reduced need for continued long-term treatment, improved ability to work and reduced care requirements.

Expertise and resources

- **We have experience in:**
 - Pharmaceutical process development
 - Process scale up
 - Process modelling across different industries
 - Working as part of larger consortia to deliver innovative projects.
- **We are looking for:** expertise and resources from a wide range in partners to support the establishment of an international framework to enable common implementation of targeted personalised treatments. This will include:
 - Supply chain
 - Regulators
 - Healthcare providers
 - Pharma
 - Diagnostics
 - Manufacturers
 - Tech providers
 - Clinicians
 - Trial providers
 - Academics
 - Insurers