Engineering and Physical Sciences Research Council

RiHN Research Funding Q&A Webinar

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Redistributed Manufacturing in Healthcare Network

Sept 2020

UWE Bristol University of the West of England

Loughborough University

Newcastle University

UCL

University of Sussex

Heriot-Watt University

King's College London

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Agenda

11.00 – 11.15	**Introduction to the RiHN programme and funding application process**
11.15 – 11.30	**General Q&A and requests for collaborations**
11.30 – 11.45	**Additive Layer Manufacturing introduction, presentation and Q&A**
11.45 – 12.00	**Cell & Tissue Manufacturing introduction, presentation and Q&A**
12.00 – 12.15	**Clinicals Fluids Manufacturing introduction, presentation and Q&A**
12.15 – 12.30	**Pharmaceuticals Manufacturing introduction, presentation and Q&A**
12.30	**Close**

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RiHN Core Team

- **Eight institutions**, spanning the sciences, engineering, policy and management
- Access to a network of **250+ RiHN members** across academia, public and private sectors
- **Thought leadership** in Redistributed Manufacturing (RDM) – professional reports, international journal publications, national cross-disciplinary workshops, novel design and breakthrough technologies

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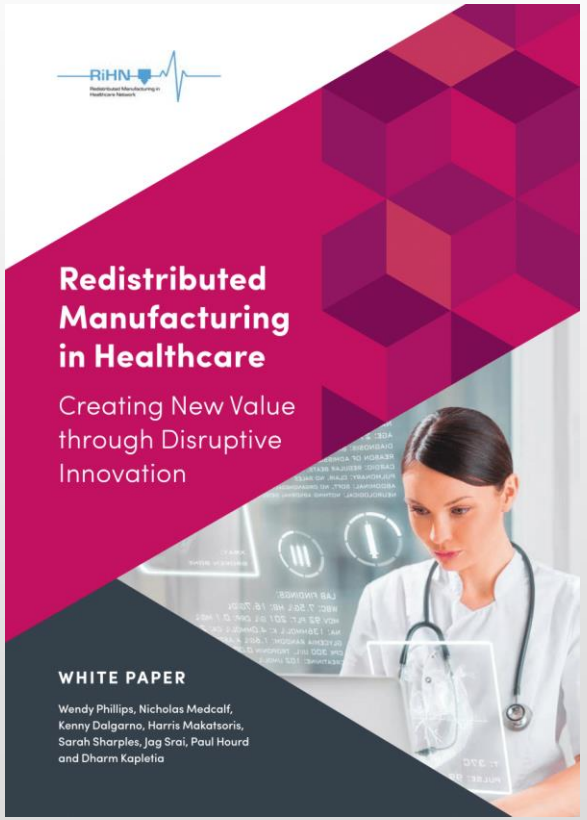
Redistributed Manufacturing in Deployed Medical Care

"An interesting future possibility would be to take RDM into ***mobile or flexible locations, in cases where there is an acute and urgent demand for medical products or supplies***, for example to meet the demands of humanitarian crises, natural disasters or emergencies. The first hours are critical for saving lives or reducing the chances of debilitating conditions; RDM systems could seek to deliver rapid diagnosis, production and testing in remote conditions."

" The factory of the future may be at the bedside, in the home, in the field, in the office and on the battlefield." (Foresight 2013)



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Network Plus Overview

"We seek to **identify, fund and advance** high-value **applications** of **redistributed manufacturing** research that will transform **future deployed medical care** capability"

- UK Engineering & Physical Sciences Research Council (EPSRC) Funded Network Plus Programme, running from July 2020 for 2 years, with up to **£1.2m* available for feasibility study funding**
- This programme provides a unique **bridge** between medical practitioners involved in military and emergency medicine and research engineers developing redistributed manufacturing (RDM) systems
- Extension of the original EPSRC Redistributed Manufacturing in Healthcare Network (2015-2017), which funded 6 feasibility studies advancing applications of RDM in **regenerative medicine, pharmaceuticals and medical devices**, and established a network of 250+ members

*@80% FEC

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Research themes

Theme 1

Military and Emergency Medicine Requirements in Deployed Operations

Theme 2

Additive Layer Manufacturing Capability

Theme 3

Cell and Tissue Therapy Manufacturing Capability

Theme 4

Clinical Fluids Manufacturing Capability

Theme 5

Pharmaceutical Manufacturing Capability

Theme 6

Innovation Assessment and Adoption for Deployed Operations

- **Funding is directed to research themes (2-5), with £300k @80%FEC available in each theme (Total £1.2m)**
- Guidance documents for each theme can be downloaded from our website: www.rihn.org.uk
- **Grant holders are expected to work with themes 1&6**
- In exceptional cases, RiHN will consider cross-theme proposals

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Pre-proposal considerations…

- Funding is for researcher time (typically 3-6 months) and associated project costs only
- Open to UK HEIs, UKRI-approved Research Institutes, NHS research bodies, Public-Sector Research Establishments (PRSEs), other organisations that meet UKRI's Independent Research Organisation (IRO) criteria

https://www.ukri.org/funding/how-to-apply/eligibility/

- Proposals are expected to have at least one [not funded] external partner (i.e. industrial, public-sector, non-governmental organisation)
- Proposed research should ideally be aimed at TRL Level 3 (proof of concept), with potential for progression and further R&D/innovation funding
- Proposed area of research should have a clear application in deployed medical care and will articulate expected clinical/operational impact

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Application process

- All proposals must be submitted using our RiHN **application form**, available on request (www.rihn.org.uk/funding/)
- First deadline for proposals is **2pm on Friday 30th October 2020**, with an expectation of a start date in January 2021
- A second funding deadline is expected in early 2021, subject to availability of funding
- All proposals will be assessed by a panel of experts, ideally within 4 weeks of RiHN call deadlines, results will be shared with feedback

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Questions and Requests

RiHN Programme and Application Process Q&A

Professor Wendy Phillips, Professor of Innovation and RiHN Programme Director
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Dr Dharm Kapletia, Senior Research Fellow and RiHN Programme Manager
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Requests for Collaborations

- Connecting research teams and external partners
- Single research institution seeking to work with others to strengthen their proposal

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Agenda – Funding themes

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Additive Manufacturing Theme

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Introduction

- The Additive Layer Manufacturing (ALM) capability research theme focuses on the development and evaluation of field deployable ALM processes for the creation of custom-fitting or personalised medical devices.
- A system's view is important, which may consider multi-use or availability of raw and novel materials to reduce logistical/storage burden (i.e. ALM inputs).
- Any ALM technique may be considered (including hybrid approaches), but processes must be capable of being, transported to, installed in and used in an environment where the value can be delivered in a deployed medical care setting

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Scope

- The clinical scope covers anything which may be encountered within a deployed medical care scenario, whether humanitarian, military or emergency
- Novel prototype devices evaluated for clinical use in deployed operations
- Proof of concept studies demonstrating cost-effective ALM manufacturing platforms technologies
- Collaboration with relevant public, private or third sector organisations is encouraged

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Expected activities

- **Methods:** Feasibility studies, Design of Experiments
- **Outputs:** Medical devices, trauma care (wound cleaning, compression, splinting)
- **Impact:** Applications at the point-of-care in remote, rural, hostile environments

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Questions

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Cell and Tissue Therapy Manufacturing

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Introduction

- **Primary focus:**
  - Identifying the points in the deployed medical care supply chain at which cell and tissue-based therapies can be used to stabilise casualties, to facilitate later treatment and to enable tissue reconstruction.
  - Exploring the desired therapeutic benefit, implementation costs and how the therapy can be integrated into the as-is patient management system.
  - Enhance manufacturing capability of cell- and tissue-based therapies to achieve the clinical outcomes listed below.
- **The desired clinical outcomes are:**
  - Reduced recovery time from burns, fracture and blast injury
  - Reduced rehabilitation times
  - Increases in the number of service personnel and civilians who achieve active life post-trauma

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Scope

- The clinical scope covers anything which may be encountered within a civilian or military deployed medical care scenario. Specific issues identified through consultation with deployed medicine practitioners include:
  - Accelerated soft tissue healing
  - Supporting nerve regeneration
  - Prevention or reduction of mal-healing or non-healing bone fracture union
  - Resolving minor but debilitating injuries such as loss of use of a hand due to scaphoid injury
  - Red blood cell production, and production of other cell types for specific applications
  - Tissue-engineering with non-immunogenic cells
  - Manufacturing technologies appropriate for a deployed setting
  - Analytical techniques which would support the application of cell and tissue therapies

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Expected activities

- **Methods:** lab or desk based studies, or a combination of the two
- **Outputs:**
  - Prototype cell, tissue or regenerative therapies and business cases with pre-clinical evidence
  - Understanding of the role and integration of proposed therapies in the military and emergency medicine treatment landscape

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Questions

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Clinical Fluids Manufacturing

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Introduction

- Clinical fluids (IV solutions, therapeutic fluids, potable/sterile water) are critical in a range of deployed medical care scenarios, yet access/quality can be limited
- Medics/First Responders are frequently limited in what can be carried, reducing the range of possible medical interventions
- Mobile medical facilities can face operational and logistical challenges around sterility, temperature-sensitive storage and the general “fragility” of clinical fluids
- **This theme invites innovative research projects to address these challenges**

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Focus

- Enhancing capability to rapidly produce intravenous or other fluids in deployed conditions.
- Pioneering new fluid manufacturing techniques or repurposing/re-engineering existing technologies for cost-effective adoption in deployed care settings
- Advancing the generation of blood products on-demand (including synthetics) or related therapeutics to stabilise casualties and to facilitate later treatment
- ‘Freedom from fridges’ – techniques that reduce, or obviate, the requirement for temperature-controlled environments to store therapeutics and clinical fluids

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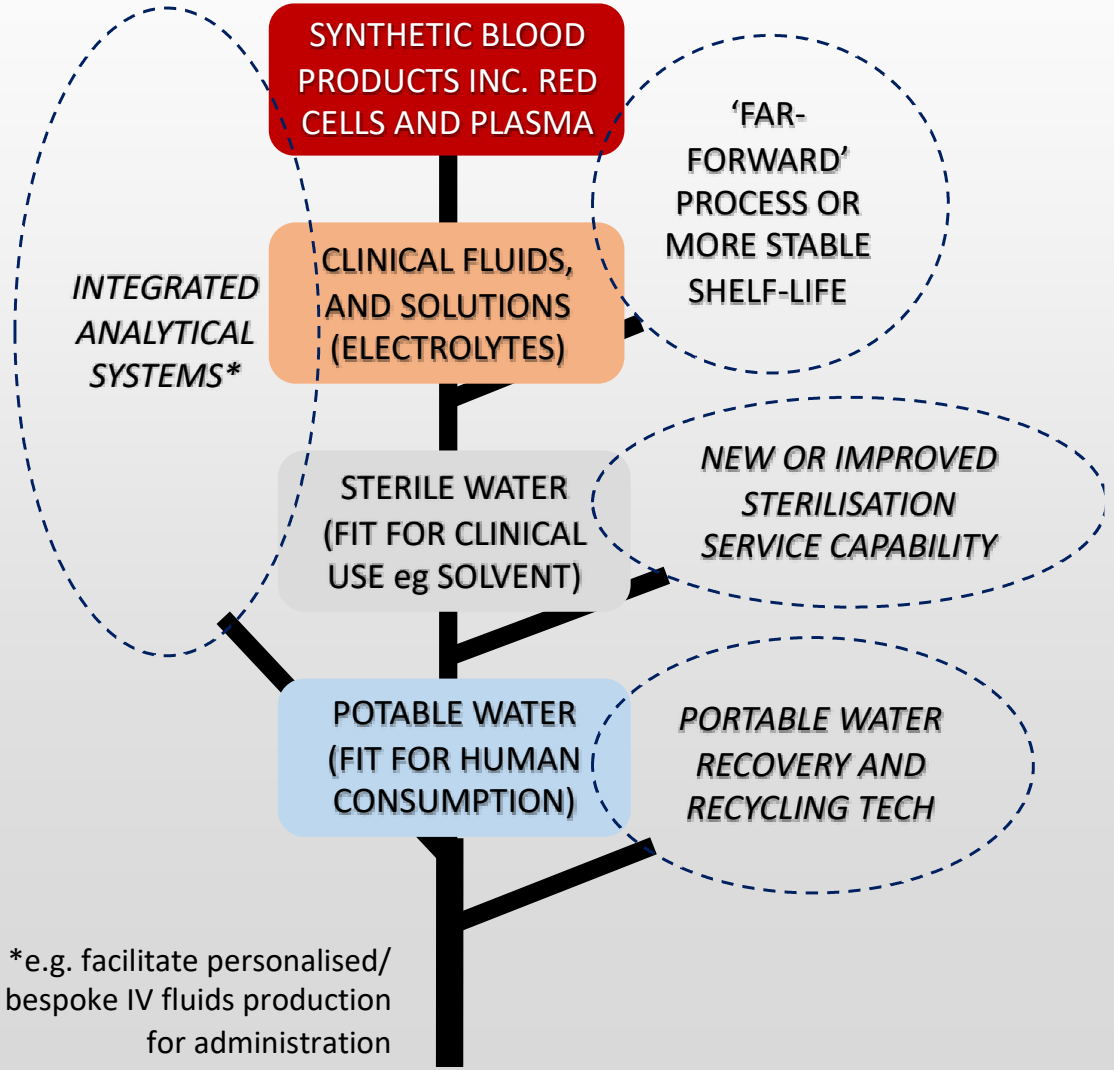
Scope

Each box representing a possible ‘stage-gate’ level of functional iterative development



*e.g. facilitate personalised/ bespoke IV fluids production for administration

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Scope (non-exhaustive examples)

- Manufacturing, bio-manufacturing and processing technologies
- Novel techniques offering mobile, 'on-demand' production and processing of potable and sterile water, clinical fluids and therapeutic solutions which reduce 'shelf-life' constraints
- Generation of 'donor-less' red blood cells and blood product substitutes
- Adapting innovative production technologies from hi-tech sectors to application in humanitarian, military and emergency medical environments
- Analytical techniques supporting efficient and effective application of clinical fluids manufacturing processes, or offering the potential for bespoke, patient-focused therapeutics (i.e. personalised intravenous fluid infusions)
- Alternatives to existing water-based sterilisation facilities; water recovery or recycling techniques to increase efficiency and support sterile service capability

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Expected activities

- Proposals must be clear as to how they demonstrate clinical value within the deployed care setting
- Projects may be feasibility studies, lab tests, proof of concept and design and can be iterative or transformative
- Projects may focus on novel technologies or the modification of existing approaches with a deployed focus
- Projects should ideally include a collaborative arrangement with an end user organisation and/or commercial partners are strongly encouraged (although we cannot fund commercial entities)

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Questions

Research theme contacts:

- Prof. Nik Willoughby (N.A.Willoughby@hw.ac.uk)
- Prof. Jonathan Benger (Jonathan.Benger@uwe.ac.uk)
- Lt Col. Paul Hunt (paulantonyhunt@doctors.org.uk)

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Pharmaceutical Manufacturing Capability

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Introduction and Objectives

- Advance the development of **miniaturised portable device platform(s) and techniques capable of producing** small-molecule active pharmaceutical ingredients (APIs), therapeutic proteins (e.g. analgesics, anaesthesia, antibiotics) or live-biotherapeutics targeting the microbiome (e.g. probiotics, biosensors), **in deployed operations**.

- Establishing proof of concept for platform(s) **capable of manufacturing single-dose levels of APIs and biologics** (adhering to regulatory standards), demonstrating high purity, efficacy, and potency in short timeframes.

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Scope of the call - bounded by three areas

1) **Rapid Live Bio-therapeutics manufacturing** (scale-up and delivery)-To advance promising approaches for the manufacture and packaging of therapeutics in the field, targeting the microbiome. E.g., pre-engineering/packaging of libraries of recombinant bacteria or spores for rapid deployment and large-scale manufacture in-situ via fermentation, in single-use fermenters.

2) **Redistributed manufacturing of bespoke Vaccines and Therapeutics**-Novel approaches for rapid vaccine and drug development and deployment locally during emergencies. E.g. yeast and bacteria fermentation and RNA type platforms using chemistry and novel extraction and purification systems for manufacturing on demand and in situ.

3) **3D Printing pharmaceuticals in emergency situations**- On-demand printing combi-pills where 3D Printing is used to combine APIs into a single tablet at the point-of-use. Exploring the barriers and enablers of 3D printing pharmaceuticals (pills, combi-pills and crystalized APIs) in deployed operations post natural and man-made disasters.

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Expected activities and outcomes

- The focus of this call for proposals is on **feasibility studies** and **proof of concepts**. Feasibility study projects are expected to provide researchers with an opportunity to **investigate and test the capability of advanced redistributed manufacturing processes** related to the three themes.
- Within the context of a dedicated manufacturing engineering feasibility study, we welcome the analysis of **data** that can help inform the rationale for **technology adoption** or **impact on pharmaceutical supply chains**.
- Studies should lead to outcomes that will underpin **further grant proposals** and collaborations.
- **Industrial partnerships are encouraged**

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Questions

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