





FUTURE TARGETED HEALTHCARE MANUFACTURING HUB
ANNUAL REPORT
2021-2022



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CONTENTS

FOREWORD	2
FOREWORD: NEW FRONTIERS.....	3
EXECUTIVE SUMMARY	4
THE HUB IN NUMBERS.....	6
HUB VISION.....	7
ACTING AS A NATIONAL HUB	11
National Hub Strategy and Outreach	12
Influencing National Policy.....	13
Influencing the Innovation Landscape.....	15
Public Engagement Activities.....	15
HUB RESEARCH PROGRAMME	17
User-Driven Hub & Spoke Research	18
Grand Challenges: Notable Achievements	21
Academic Engagement Beyond the Hub	23
HUB USER ENGAGEMENT.....	26
Collaborator Engagement.....	27
User Feasibility Studies: Enhancing Knowledge Exchange.....	30
User Feedback on Hub Impact	31
Wider Engagement and Benefits	33
DEVELOPING THE HUB TEAM	34
Hub Researcher Perspectives	35
Innovative Working Practices.....	36
Equality, Diversity and Inclusion (ED&I).....	37
HUB DIRECTORY.....	38
Hub & Spoke Academic Team.....	39
Hub User Partners	48
EVENTS AND PUBLICATIONS	52
Hub Events 2021	53
Selected Hub Publications.....	54
FINANCES	64
Leveraged Funding.....	65

FOREWORD

The past year has been one of considerable change for the Hub. Emerging from the impact of Covid on lab accessibility and face-to-face networking, the Hub faced a new landscape for biologics manufacturing that had changed radically in the wake of new vaccine advances. Successful navigation of the EPSRC mid-term review with resoundingly positive feedback, also brought the Hub into phase 2 of its programme that will define its final three years. As this phase coincided with the post-pandemic era, it was timely to review how the Hub research should adapt to this new landscape. To address this, the Hub undertook an extensive consultation with stakeholders across industry, healthcare and academics, to evaluate the impact of the first phase of research and Hub activities, and then also so identify the major new challenges that the Hub could address to provide the most impact possible for a newly-shaped UK and global manufacturing industry.

Engaging Hub researchers with the Covid vaccines development effort brought new skills from viral vector vaccines manufacturing and formulation, that could now be applied towards gene therapy manufacturing challenges in phase 2. The accelerated regulatory acceptance of viral vectors and mRNA-carrying lipid nanoparticles in response to Covid has opened up new possibilities for gene therapy, and brought many new products much closer to patients, yet it has also exposed many major bottlenecks and technical challenges that need to be addressed. For example, manufacturing for smaller populations needing gene therapy presents challenges with economies of scale. In addition, the modification of viral vectors and lipid nanoparticles required for targeting specific cell types with gene therapies, will bring additional complexity to the constructs and associated manufacturing challenges.

As the world begins to open up again, the Hub is planning hybrid meetings to allow those comfortable to meet face to face again, while also retaining the new-found capability to network more effectively with global collaborators. Attendance at the User Steering Committee and Specialist Working Groups has continued to grow, and new members have joined demonstrating how the Hub has established its position as a major innovator and influencer in the sector.

Dr Stuart West

Chair
Hub Advisory Board



FOREWORD: NEW FRONTIERS

In many ways 2021 was the year of the virtual world and the Hub responded creatively and flexibly to the demands of the second year of the Pandemic developing and refining new modes of working, networking and interacting with its partners throughout the year. It continued to demonstrate its critical importance as a leading and nurturing part of the UK's world class bioprocessing capability.

In the first year of the Pandemic the Hub reached its halfway point and working collaboratively with its Users formulated and established plans for the second phase of its activity which saw implementation in 2021. The planned 2020 mid-term review by EPSRC was delayed by the pandemic and was completed with great success in 2021.

The Hub has built and grown a rich and engaged network of Industry Users which reads like a who's who of British based biotech and biopharma companies. It has grown from 34 organisations on inception to 45 in 2021. That new partners are being added all the time is a clear demonstration of the continuing relevance of Hub research to its User base.

One of the key ways in which the Hub interacts with its Users is through its Specialist Working Groups (SWGs). In these SWGs, researchers and Users meet to share thoughts on research results and future research themes in an open and collaborative way. SWGs have proved to be an excellent mechanism for fostering networks and encouraging collaborations. A notable feature of SWGs has been a consistent stream of high-quality contributions into them from Users. Recent examples include inputs from CPI on 'mRNA synthesis' and Kent on 'Next generation CFS systems' (Cell-Free Synthesis SWG); Kymab-Sanofi on 'Drug product development' (Formulation SWG); UCL Cancer Institute on 'Clinical response of CAR T in ALL adults' (Regulatory, Reimbursement & Policy SWG) and AstraZeneca on 'Gearing up capacity for pandemics' (Digital Decisional Tools SWG).

The pandemic and associated lockdowns have reduced the opportunity for face-to-face contact but the SWGs have adapted and prospered in virtual form throughout 2021 and extremely effective, well attended interactive meetings enabled by use of tools such as Teams, Zoom, Slido and Miro Whiteboards have been held by all the SWGs.

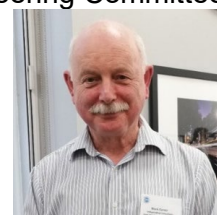
The Hub held major Summer and Autumn User group meetings in 2021. Both were held virtually and were well and enthusiastically attended by Users and academics. The Summer meeting was a 'Spotlight on Gene Therapy Manufacture: Challenges and Opportunities' with keynote presentations from Professor Stephen Hart (mRNA) and Professor Farzin Farzaneh (viral vectors). Hub research was showcased in PI and PDRA presentations. Developing policy in the field was explored and users were consulted on the direction of views on future research using virtual polling mechanisms. The Autumn meeting in November had as its centrepiece a series of Interactive workshops on: Scientific, Financial and Regulatory Challenges in Personalised Medicine; T-Cell and Viral Vector Experimental and Data Mining; Supply Chain and Economics for Cell and Gene Therapies; Development of AAV-based therapeutics. The meeting was closed by a Keynote presentation on 'Industry 4.0 for Biologics. Learning across the Manufacturing sector' by Professor Sam Turner.

The Hub plays an increasingly important role in influencing thinking on regulation and policy development affecting novel medicines. It held a workshop in June 2021 on 'Regulation for POC manufacture of ATMPs' with input from MHRA. Output from this workshop included a formal response to the MHRA's 'Consultation on Point of Care Manufacturing'. This was followed in September 2021 by a workshop on ethics of personalised medicines which led to a feasibility call'.

As we exit 2021 we can look forward to increased face-to-face interaction and the resumption of more normal (although probably changed) engagement in 2022. The research challenges of the second phase of the Hub will be met and thoughts and plans will turn to the next phase of bioprocessing research at UCL and its collaborators and the challenges of how we can bring better medicines more effectively to society.

Dr Mark Carver
Chair

Hub User Steering Committee



EXECUTIVE SUMMARY

In 2021-2022, the Hub continued to reinforce its position as a leading national hub in the targeted healthcare manufacturing space. This was recognized by the mid-term review panel in February 2021 that acknowledged the “world-leading research undertaken in the Hub”, “high level of industry engagement”, “positive research culture” and that “the Hub successfully demonstrated that it acts as a national focus for targeted healthcare research”.

The Hub’s position was further cemented by its continuing influence on the national policy agenda to help the UK respond to future opportunities in medicine manufacture. This included contributing to the MHRA’s new regulatory framework for point-of-care manufacture of ATMPs, participating in the G7 100 Days Mission roundtable hosted by the UK Government Chief Scientific Advisor Sir Patrick Vallance, and contributing to the Parliamentary committee inquiry report on “Coronavirus: lessons learnt”.

On the recommendation of the Hub’s mid-term review panel, the Hub also held a workshop in September 2021 to explore ethical issues related to personalised medicine manufacture. This was further built upon with a call for ethics feasibility studies that has led to the building of links between ethics experts from the University of Oxford, Vienna and UCL.

On the core research innovation front, the Hub progressed in full force into Phase II of the research programme designed to adapt to the continually evolving biologics manufacturing landscape. The timely and strategically relevant research agenda was co-developed with all key stakeholders including industry users, regulatory bodies and academics, through a series of structured engagement processes. Whilst Phase I of the Hub focused on stratified proteins (e.g. ADCs) and personalised cell therapies (e.g. CAR T-cell therapies), Phase II is now addressing a broader set of modalities that include viral vectors for gene therapies and nucleic-acid based products therapies (pDNA, mRNA). In addition, new themes have been added in digitalisation and analytics, which had been identified as areas for growth in a Hub gap analysis.

Over the past year, the Hub has made significant progress in addressing a set of key research questions. In Grand Challenge 1 on digital decisional tools, the research spans cost of goods, cost of development, supply chain logistics, regulatory and reimbursement strategies, through to data mining and control. Pioneering work is building the tools to identify the optimal supply chain logistics and economics for CAR-T therapies and viral vectors, map out the regulatory challenges for point-of-care manufacture, determine the cost-effectiveness of CAR-T therapies to the health service, and to develop digital twins for these new modalities. In Grand Challenge 2 on digitally-driven manufacturing, the research spans experimental and analytical platforms for both acellular and cellular bioprocessing for cell and gene therapies. Platforms are being developed to explore the potential of novel cell-free synthesis platforms for plasmid DNA manufacture, to optimize AAV manufacture from capsid engineering through to formulation, and to address the analytical gaps to assess viral vector quality and stability.

User engagement has continued to be a hallmark of the Hub work. Full participation in our bi-annual meetings for the User Steering Committee and the 5 Specialist Working Groups has been supplemented with webinars and technology showcases to create a rich and diverse calendar of engagement opportunities. These meetings provide critical opportunities for knowledge exchange, sharing of the latest Hub research insights and learning about sector trends from invited keynotes and roundtable discussions. The Hub’s active industry consortium now stands at 45 members and in 2021 we welcomed 2 new members: Repligen and CSL.

User feasibility studies have enabled us to build valuable collaborations with partners. We have also established a number of impact user case studies to

Professor Suzanne Farid

Hub Co-Director



Professor Paul Dalby

Hub Co-Director



Professor Nigel Titchener-Hooker

Strategy Director



demonstrate the impact of Hub tools to users, notably with Ipsen on cell-free synthesis for neurotoxins, Oxford Biomedica and BIA MAC on viral vector manufacture and Albumedix on formulation. The impact case studies highlight benefits ranging from informing business cases and priority shifts in investment decisions through to impacting the national agenda and promoting further research partnerships.

The achievements of our PDRAs and associated doctoral students are integral to the Hub's success. We have continued to support our vibrant and highly connected cadre of researchers. They in turn continue to make impressive advances, generate novel insights, produce high impact publications and to present at global conferences. Such dissemination is key to their career progression and provides yet more evidence of the effectiveness of the EPSRC Hub and Spoke mechanism to take the UK forward to a world-leading position for manufacture in the targeted healthcare sector.

THE HUB IN NUMBERS

To June 2022

26



Academic Researchers
Across 6 Leading Universities



45

Industry & Sector
Partners

87



Meetings, Workshops
& Networking Events



142

Aligned PhDs & EngDs

114



Conference Presentations



173

Publications

45



Feasibility Studies



£28m

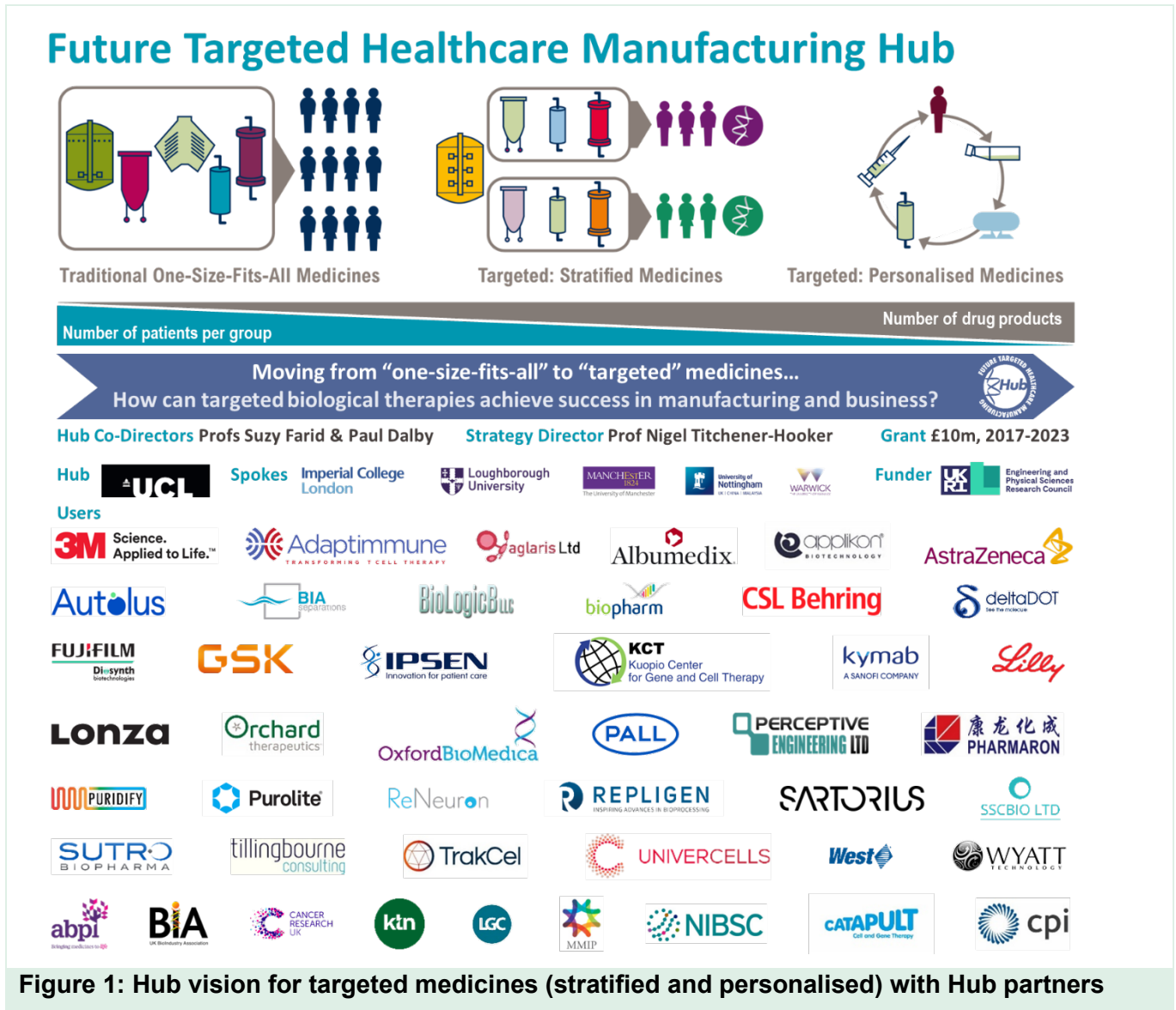
Leveraged Funding

HUB VISION



Mission

By 2025 targeted biological medicines will transform the precision of healthcare prescription, improve patient care and quality of life. The current “one-size-fits-all” approach to drug development is being challenged by the growing ability to create stratified and personalised medicines targeted to specific sub-populations and even individuals. Without significant manufacturing and supply innovations, the promise of targeted healthcare will remain inaccessible for many. The impact on health and well-being is profound. The Hub mission is to act as a **National Hub and Spoke collaboration to take the UK forward to a world-leading position for manufacture in the targeted healthcare sector** (Figure 1).



Vision

Our vision is 3-fold:

- (i) **To be the first globally recognized consortium** for the creation, delivery and dissemination of innovative manufacturing research, underpinning cost-effective, robust manufacture, supply and delivery of targeted biotherapeutics;
- (ii) **To provide the manufacturing infrastructure and capabilities** needed to enable UK manufacturers to exploit advances in precision medicine, through new technologies, skilled personnel, IP and spin-outs;
- (iii) **To enhance UK competitiveness** in this new era with a programme of Grand Challenges that create and combine decisional tools and manufacturing innovations.

Capacity to Deliver Vision

We have assembled a **Hub and Spoke team** with an unrivalled track record of delivery to drive forward the vision. The **Hub** is hosted in UCL Biochemical Engineering with leading academics with expertise in protein and cell therapy biomanufacturing, decisional tools, data mining, analytics, microfluidics. Wider host institution partners bring in expertise across UCL in health economics, regulation and public policy as well as extensive links with hospitals and patients. The **Research Spokes** are experts from the leading UK university groups that provide complementary expertise in formulation for drug delivery (Nottingham), cell therapy modelling (Loughborough), operational research (Warwick), supply chain optimization (Imperial), and process control (Manchester). Thus, the Hub and Spoke team have the capacity to deliver the timely vision by linking biomanufacturing strategies to the broader consequences on all these fronts. **We have a platform of activities** to network academics, industrial users, regulators and clinicians to deliver outreach and impact broadly. Consequently, the Hub is driving forward the national research and innovation agenda in this sector and engaging with the entire value chain, including the relevant Catapult Translational Spokes (CPI, CGTC) and industry, to ensure acceleration of impact and benefit to society and to the UK economy. The vision fits closely the ambitions of the Hub and Spoke **institutional strategies** related to improving “Global Health” by creating tools to enable targeted healthcare.

Vision Review and Refresh

The Hub Management Group set up a **regular cycle of consultations** with industry users, national agencies, regulatory authorities, health technology assessors, and independent external experts. More specifically, the vision was reviewed and refreshed in response to the changing landscape via the User Steering Committee (2 per year), Advisory Board (2 per year), five Specialist Working Groups (each running twice a year) and a special Hub Phase II Planning workshop with senior executives from the user community.



ACTING AS A NATIONAL HUB



National Hub Strategy and Outreach

The framework for Hub outreach to leverage the Hub achievements and realise the mission to act as a world-leading National Hub and Spoke collaboration are outlined in Figure 2. The Hub leads the national research and innovation landscape in this sector by engaging with the entire value chain including translational stakeholders (Innovate UK, Catapults) through to industry to ensure acceleration of impact.

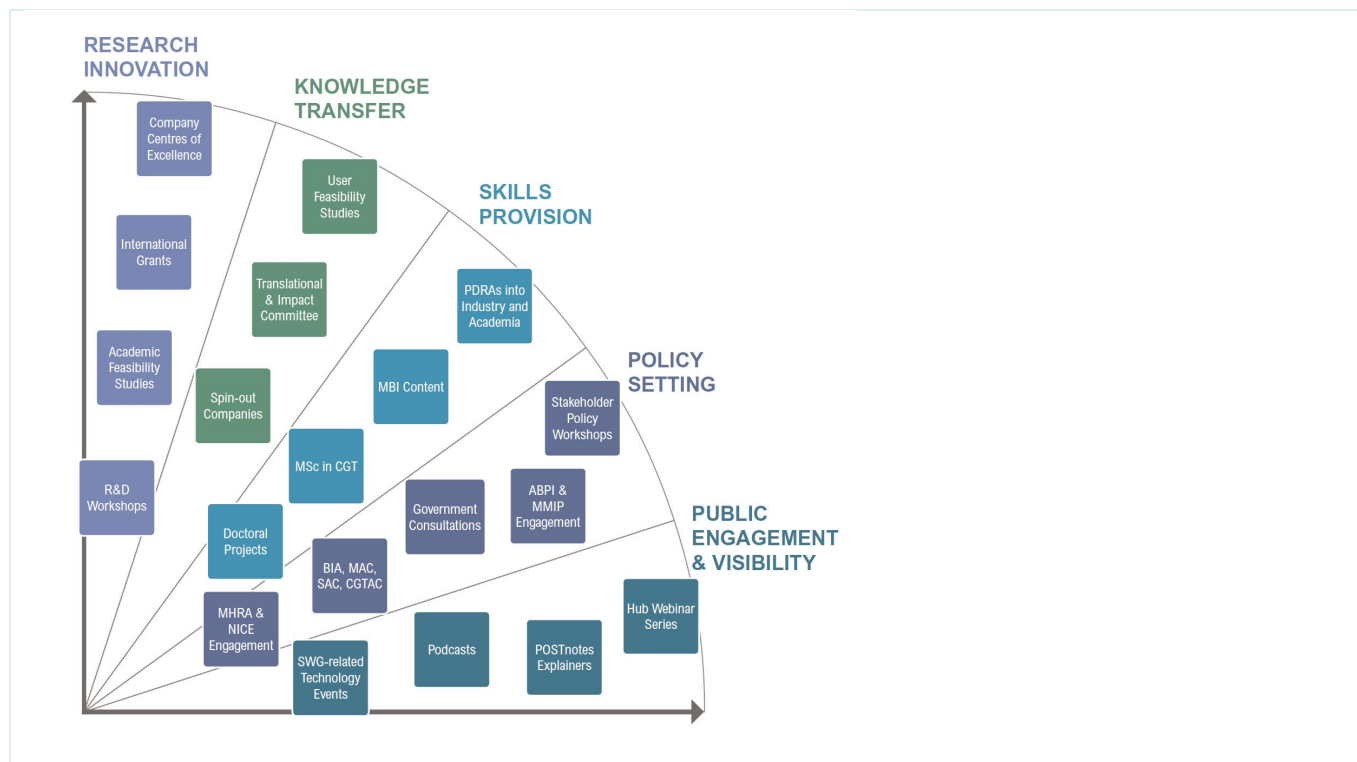


Figure 2: Framework for Hub outreach activities to develop a National Hub strategy

The key deliverables relate to:

Research Innovation (see The Hub Research Programme section):

- Decision-support tools to transform supply chain economics for targeted healthcare
- Novel manufacturing, formulation and control technologies for stratified and personalised medicines.

Knowledge Transfer (see Hub Engagement with Users section):

- Network of academics, industrial users, translational spokes, regulators and clinicians to drive forward the national research and innovation agenda
- Providing the engineering infrastructure needed for sustainable healthcare and enhanced UK competitiveness.

Skills Provision (see Developing the Team section):

- Technologies, skill-sets and trained personnel needed to enable UK manufacturers to embrace fully the opportunities offered by advances in medical precision and patient screening.

Policy Setting & Public Engagement (see sub-sections below):

- Hub expertise leveraged to contribute to matters of national importance and to influence policy.
- National resource raising the profile of high value manufacturing research in the UK.

Influencing National Policy

Throughout 2021 the Hub continued to act as a thought leader in the life science manufacturing industry, helping ensure the UK is ready to respond to future opportunities in personalised medicine manufacture, contributing to a prosperous UK.

The Hub has engaged with Government bodies to influence the national policy agenda:

- The Medicines and Healthcare products Regulatory Agency (MHRA)** - Hub academics took part in a range of activities to help the MHRA shape a new regulatory framework for point-of-care manufacture of Advanced Therapeutic Medicinal Products, (ATMPs) and other medicinal products. This included contributing to the MHRA's stakeholder workshops to shape the regulatory proposals (March 2021), running our own workshop focussed on the application of the framework to ATMPs (June 2021), and responding to a public consultation with the findings of our workshop (September 2021). Irina Brass and Edison Bicudo from the Hub's Regulatory Strategies team and Hub Policy Advisor Penny Carmichael online workshop on the concepts and rationale of the point of care (POC) manufacturing regulatory framework convened 32 specialists in the field of biotherapeutics, manufacturing technologies, and regulation. Through a series of roundtable discussions, participants explored challenges of applying the regulatory framework to cell and gene therapies manufactured at POC. Keynote talks were given from representatives of the MHRA, Lonza and Hub Co-Investigator Qasim Rafiq (June 2021). A report of the workshop can be found on the [UCL website](#). A version of this report was also published in [Cell and Gene Therapy Insights](#).

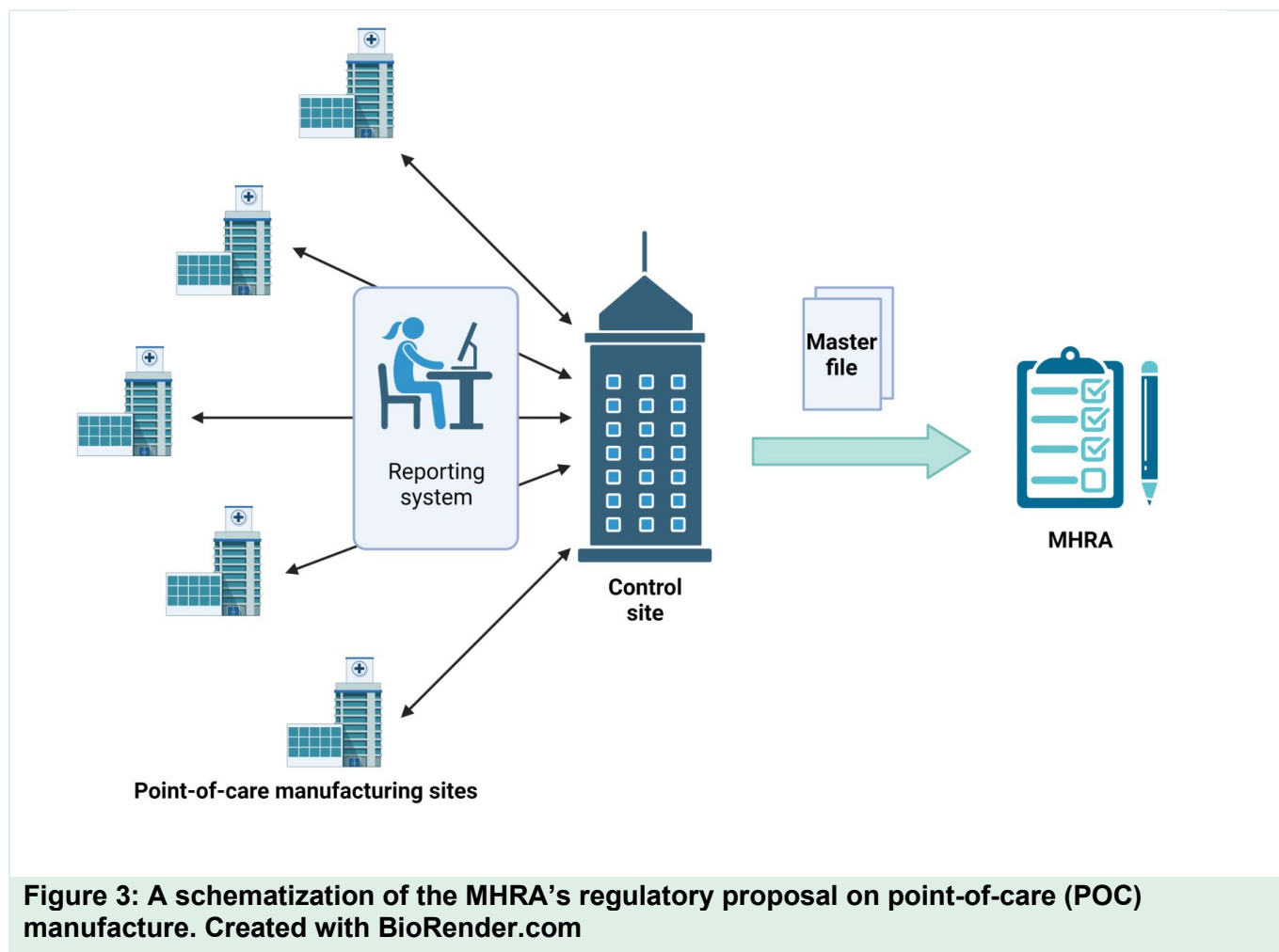
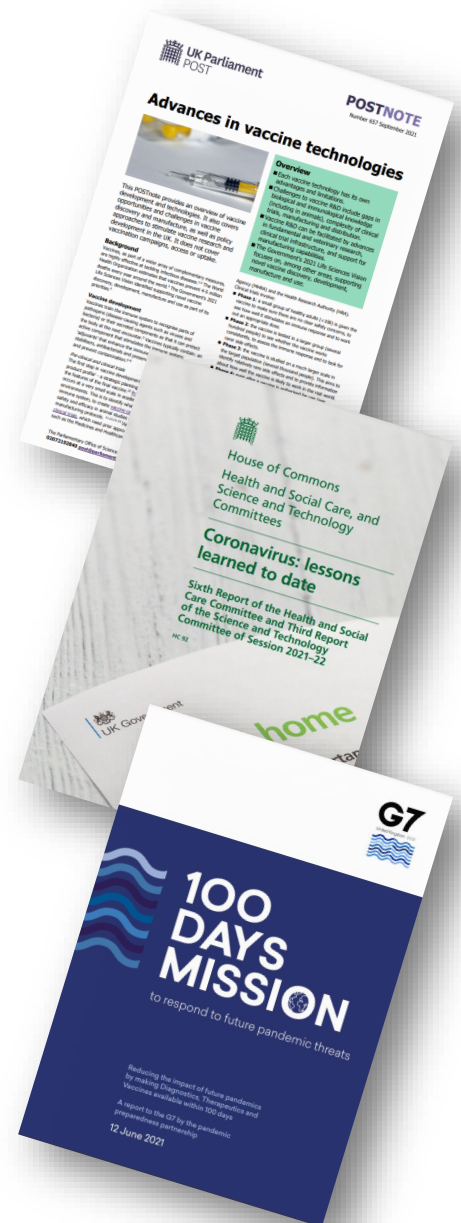


Figure 3: A schematization of the MHRA's regulatory proposal on point-of-care (POC) manufacture. Created with BioRender.com

- Parliamentary roundtables** - Hub Co-director Suzy Farid participated in the Policy Connect “The Future of Medicine?” [Parliamentary roundtable](#) hosted by Daniel Zeichner MP to help raise awareness among policy makers of the barriers and opportunities associated with cell and gene therapies. (June 2021)
- Expert missions** - Hub academics were involved in a UKRI/KTN Global Expert mission on "The Future of UK and Canada Collaboration in Advanced Therapies". This involved taking part in a virtual visit from Canadian delegates to the UK, including Health Canada, the CellCAN and Centre for Commercialization of Regenerative Medicine networks, and representatives from leading Canadian Universities, where the Hub presented on its operating model and research priorities, and held one-to-one meetings with key stakeholders to explore collaboration opportunities.(October 2021)
- Ethics** - The Hub held an online workshop to uncover ethical issues related to the manufacture and use of personalised medicines, and identify areas for further investigation to ensure that ethical principles are “baked-in” to in the development of new manufacturing technologies (September 2021)
- POSTnotes** - The Parliamentary Office for Science and Technology (POST) [published a POSTnote](#) (a four-page briefing aimed at Parliamentarians reviewing emerging areas of research) providing an overview of vaccine development and technologies. The note also covered opportunities and challenges to vaccine discovery and manufacture, as well as policy approaches to stimulate vaccine research and development (R&D) in the UK. Hub Co-director Paul Dalby was acknowledged for his contribution on vaccine formulation. (September 2021)
- Parliamentary inquiries** - The Parliamentary committees for Science and Technology (Commons) and Health and Social Care (Commons) published their sixth report from the joint inquiry into ‘[Coronavirus: lessons learned to date](#)’. Hub Investigators Dan Bracewell and Paul Dalby [provided input on the importance of vaccine manufacture](#) to a wide-ranging UCL response which was cited in the report. (October 2021)
- 100 Days Mission** - Hub Co-director Suzy Farid [attended an invitation-only roundtable](#) hosted by the UK Government Chief Scientific Advisor Sir Patrick Vallance on the UK’s implementation of the G7 [100 Days Mission](#). Suzy provided input relating to the goals for developing new monoclonal antibody therapies during a pandemic. Two of her papers, one written with Hub Researcher Chris Stamatis, were cited in the report and her contribution helped the government set evidence-based cost targets for this type of therapy. (November 2021)



Influencing the Innovation Landscape

The Hub engaged with key sector policy influencing and roadmapping bodies, to influence the national research agenda:

- **BioIndustry Association (BIA):** Our USC Chair, Mark Carver, chairs the BioIndustry Association's Science and Innovation Advisory Committee (SIAC), and provides a link to the sector roadmapping exercise that he is coordinating to define the current UK capabilities, challenges and gaps in sector funding. Farid and Rafiq (UCL) sit on the BIA Manufacturing (MAC) and Cell & Gene Therapy (CGTAC) Advisory Committees.
- **Association of British Pharmaceutical Industries (ABPI)** – Hub Advisory Board representative for ABPI, providing two-way communication on sector needs.
- **Medicines Manufacturing Industry Partnership (MMIP)** - The MMIP provides a single UK industry voice and point of engagement with government to facilitate the growth in medicines manufacture in the UK. We have engaged in a number of meetings with MMIP, the associated and newly commissioned MMIC, and their partners CMAC, to build future links in areas of mutual interest. Contributor to the MMIP Skills Workstream.
- **BioProNet.** Dalby (UCL) is a committee member of this >500-member Network from across the UK academic and industrial community. It plays a key role in roadmapping the capabilities and challenges of the bioprocessing sector from the life sciences perspective. It is closely linked into the BIA roadmapping exercise led by Mark Carver.
- **EPSRC Manufacturing the Future Strategic Advisory Team (SAT) and Early Career (EC) Forum** - Dalby (UCL) is a committee member of this SAT within EPSRC, which advises on the health and future strategic direction of the Research and Training Portfolio within the Manufacturing the Future Theme. Rafiq (UCL) served as a committee member of the EC forum in Manufacturing Research to shape the Manufacturing the Future research agenda.
- **BBSRC Biopharmaceutical Steering Group** – Bracewel (UCL) which advises on priorities, frameworks and business cases for research and innovation.



Public Engagement Activities

As a unique national resource in manufacturing research for the biopharmaceutical sector, we have sought to build the profile of high value manufacturing research in the UK via the following routes:

- **Podcasts and webinars** - e.g. Maria Papathanasiou, Tech for Pandemics online lesson for Kids, March 2021
- **Sector training** - e.g. Qasim Rafiq, Cell and Gene Catapult's Morning Tips, May 2021
- **Global investor forums** - e.g. Penny Carmichael, UN World Investment Forum, March 2021
- **Therapeutic Innovation Networks** with scientists, clinicians and engineers - e.g. Qasim Rafiq, Paul Dalby, January and June 2021
- **Newsletters** - The Hub sends out biannual newsletters to its User and academic network, as a key mechanism for updating on Hub progress, and raising awareness of key dates and calls for the User Feasibility Studies.



HUB RESEARCH PROGRAMME



User-Driven Hub & Spoke Research

The Hub’s manufacturing research updated for July 2020 is arranged within the two Grand Challenges (GCs):

- **Grand Challenge 1 (GC1): Digital decisional tools for transforming supply chain management for targeted medicines** investigated the business potential of game-changing technologies for commercial feasibility, regulatory consequences and affordability for healthcare systems;
- **Grand Challenge 2 (GC2): Digitally-driven manufacturing and analytical platforms for targeted medicines** established new technologies with the potential for radical re-design of manufacture.

The Hub Grand Challenges, with research themes, components and modalities, are summarised in Figure 4.

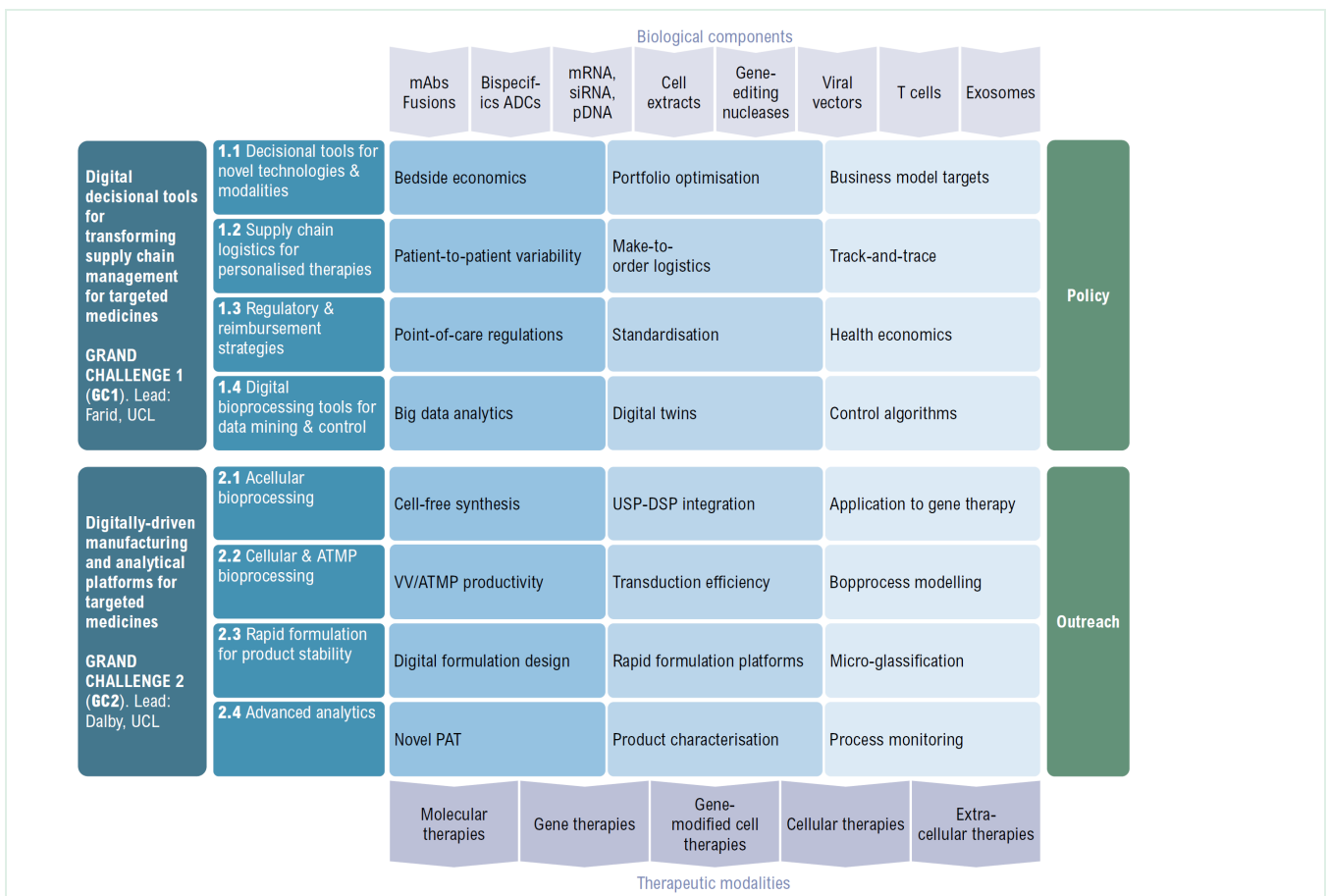


Figure 4: Schematic of the Hub Research Programme and Grand Challenges (July 2020-Dec 2023)

Grand Challenge Research: 65% of effort has been directed towards these two user-driven Grand Challenges at TRL2-4 and significant leverage has been exerted through interactions between the Grand Challenges. For example, GC1 has highlighted cost drivers and performance targets for novel manufacturing technologies that have helped prioritise experimentation in GC2 on cell-free synthesis and CAR-T cells and led to establishing novel technologies capable of achieving these quantified targets. Insights from such Hub interactions have helped to ascertain the most promising manufacturing innovations and provided the capacity to “future-proof” supply chains for targeted medicines. The Hub has enabled an integration of disciplines to a level that could not be delivered by separate projects, as further highlighted by the RA-centric connectivity diagram (Figure 5). This illustrates the internal and external connectivity of the Grand Challenge RA projects, doctoral training projects, and industrial and academic feasibility studies across disciplines themes and workstreams. These relationships maximise the impact and utility of research outcomes.

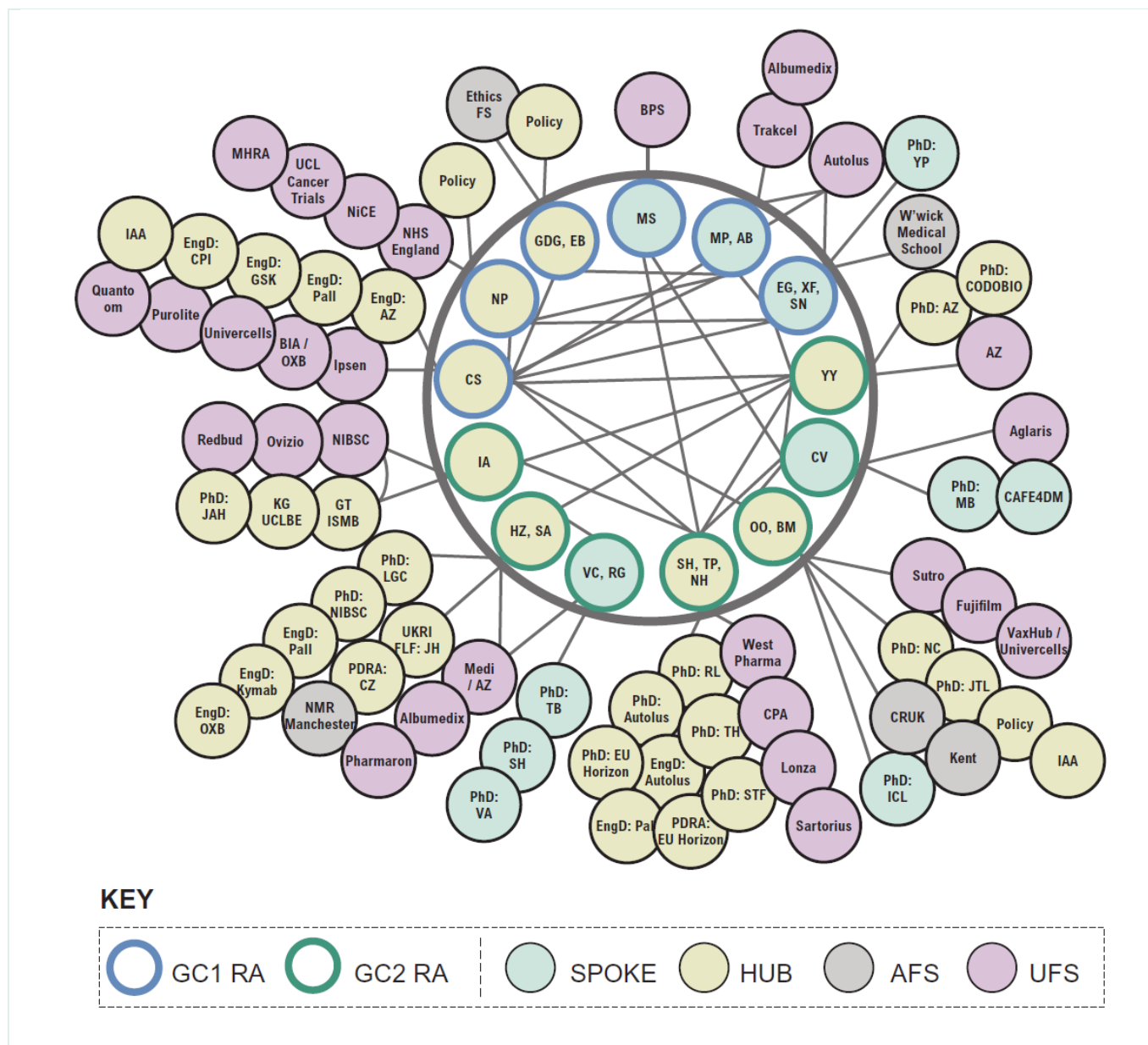


Figure 5: RA-centric view of project connectivity with the associated feasibility studies and aligned doctoral projects across the Hub and Spoke universities. RA = Research Associate, AFS = Academic Feasibility Study, UFS = User Feasibility Study

Platform Research and Impact: 35% of the Hub effort has been directed to Platform, Operational, and Pathways to Impact activities, with feasibility studies, at a network of academic (TRL2), industry and Catapult collaborators (TRL3-6), and the introduction of Policy briefings through the new appointment of a Policy researcher. Integration of these approaches has provided an integrated enterprise, manufacturing and policy-setting perspective where the opportunity is to achieve radical innovation that greatly exceeds the sum of the isolated research areas and where the linkage of research and knowledge transfer enables a step change in the industry. This has ensured that we maximise the impact of EPSRC investment over the Hub lifetime and create sustainability, and has helped the sector to respond effectively to the shifting innovation landscape, particularly around Advanced Therapy Medicinal Products, and recombinant protein-based vaccines for COVID-19.

Grand Challenges: Notable Achievements

Exceptional progress in these Grand Challenges has delivered notable achievements in 2021 facilitated by significant stakeholder engagement, summarized below.

GC1: Transforming Supply Chain Management & Economics for Targeted Medicines

Novel manufacturing- and enterprise-level computational tools have been created to determine the technical, regulatory and supply chain innovation required for commercial feasibility of targeted medicines, whilst ensuring affordability. The tools span decision-making across process development, clinical manufacturing and market supply for stratified protein and personalised cell/gene therapy medicines. Achievements in the GC1 research themes include:

- **Cell-free synthesis (CFS) economics:** Feasibility study comparing the cost and operational competitiveness of a CFS process relative to a cell-based process for highly potent recombinant neurotoxins (Olughu, Stamatis *et al.*, BioProcess International, submitted).
- **Process change economics for viral vectors:** Case studies determined the economic consequences of switching from a traditional to a scalable process for the manufacture of lentiviral and adeno-associated viral vectors (Stamatis *et al.*, 2022, in prep).
- **CAR T-cell process and supply chain economics:** Decisional tools built to evaluate the trade-offs between fresh and cryopreserved apheresis material on the cost of goods across the supply-chain (Stamatis *et al.*, in prep).
- **CAR T-cell supply chain optimisation:** Effect of storage upstream of the manufacturing facility has been characterised in terms of potential cost reductions and increased average facility utilisation. Trade-offs between cost and delivery time have been identified ([Bernardi *et al.*, 2022, Computers & Chemical Engineering](#)).
- **ATMP supply chain challenges and opportunities:** In-depth analysis of ATMP multi-level supply chain interactions ([Sarkis *et al.*, 2021, Current Opinion in Chemical Engineering](#)) and the role of process systems engineering tools ([Sarkis *et al.*, 2021, Processes](#)).
- **Factory floor scheduling for CAR T-cell manufacturing:** An algorithm to schedule the batches and assign limited resources to CAR T-cell manufacturing tasks maximising throughput while considering the uncertainties in expansion durations and patient drop-outs.
- **Regulation:** The main regulatory, infrastructure, and institutional challenges of point-of care manufacture have been identified, including an analysis of the ways in which various stakeholders can help to streamline the regulation of the manufacture, processing, and delivery of cell and gene therapies in clinical settings ([Bicudo *et al.*, 2021, Cell & Gene Therapy Insights](#)).
- **Reimbursement:** NICE's approach to appraising CAR T-cell therapies has been expanded to include recent approvals and analysed for its longer-term feasibility and budget impact (Patel *et al.*, in prep).
- **Data analytics:** Data mining tools have been developed for biomarker stratification to help clinicians make personalised decisions ([Yang *et al.*, 2022, Computational & Structural Biotechnology Journal](#)) and for protein aggregation prediction ([Zhang, Yang *et al.*, 2021, Computational & Structural Biotechnology Journal](#)).

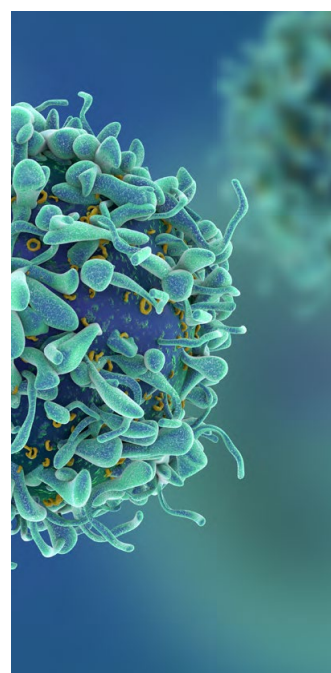


- **Adaptive control and digital twin developed:** Developed control methodologies to improve productivity ([Barton, Duran-Villalobos, Lennox, 2021, Journal of Process Control](#)) and a T-cell growth simulator designed to test new control and hybrid modelling approaches.

GC2: Sustainable Manufacturing for Future Targeted Medicines:

New technologies have been established with the potential for radical re-design of manufacture. Novel bioprocesses, analytics and control algorithms have been created that enable robust, safe and cost-effective manufacturing and formulation of stratified protein and personalised cell therapies. Together these provide the flexibility and speed to produce medicines for small patient populations or individuals in response to clinical diagnostic data. Achievements in the GC2 research themes:

- **Co-formulation:** Multiple case studies with antibodies and bispecifics have established the impacts of protein co-formulation. Established core techniques as a basis for future digital formulation capability ([Zhang & Dalby, 2020, Scientific Reports](#)).
- **Analytics:** Polymeric particles similar to viral particles in terms of size have been utilised to mimic the *on chip* behaviour of AAV in a microfluidics device.
- **Analytics:** Our new microTRF instrument has now been shown to be able to detect and quantify empty and full AAV capsids.
- **Analytics:** Machine learning approaches demonstrated that protein thermal melt stability is encoded in native fluorescence spectra at lower temperatures ([Zhang et al, 2021, Comp Struct Biotech J](#)). This will accelerate formulation screening.
- **Cell-free synthesis:** A novel protocol has been developed for the in-house acellular production of pDNA, free of bacterial sequences. This allows rapid production of high titres of pDNA within hours, and shows a superior performance to the batch reactor format in this respect. Further developments including commercialisation, academic projects and collaborations both within and outside the Hub, are being pursued.
- **CAR T-cell manufacturing and process intensification:** Successfully established a perfusion process for CAR-T production resulting in 6x increase in yield
- **CAR T-cell manufacturing and process intensification:** Feasibility study investigating culture surfaces for cell growth; evaluation of CZ 96 well treated and non-treated plates for cell culture.
- **CAR T-cell predictive models:** An ODE model was constructed to predict T-cell bioprocess outcomes from process input parameters. Predictions determined the minimal glucose feed required for healthy cell growth, and collaboration with Biopharm Services I linked this to reduced cost of goods. ([Shariatzadeh et al., 2021 Biotechnology Progress](#)).
- **T-cell analytics:** Digital holographic microscopy provides on-a-chip rapid analytics to discern activated from non-activated T-cells. Raman spectroscopy allows discrimination between different immune cells (e.g. Jurkat and primary T cells) and different states of human T cells (e.g. activated vs non-activated). Microfluidic devices for personalised health manufacturing ([Marques et al., 2020, Journal of Chemical Technology & Biotechnology](#)).



Academic Engagement Beyond the Hub

Academic feasibility studies

Funding was awarded to UKRI-eligible academic researchers for projects that complement the Hub's core research programme and broaden the impact of current work to new areas. These establish collaborations with the wider academic community and enable a strategic evaluation of emerging technologies that have the potential to address the key manufacturing research challenges of the Hub.

Table 1: Academic Feasibility Studies supported in 2021-22

Partner University & Department	Topic
Imperial College London Life Sciences	An electron microscopy platform to improve manufacture of viral vector-like biotherapeutic delivery systems
University of Kent Biosciences	New to nature natural products for sustainable antibody drug conjugate (ADC) biomanufacturing
University College London Biochemical Engineering	T cell profilomics: towards simple transcriptomics predictors of expanded t-cell functionality
University of Warwick Engineering	Identifiability of fundamental models of ATMPs manufacturing

Strategic feasibility studies: ethics

Funding was awarded in conjunction with a strategic workshop to support the exploration of key ethical issues and research questions related to the development, manufacture and implementation of personalised medicines.

Table 2: Strategic Feasibility Studies/Ethics supported in 2021-22

Partner University & Department	Topic
University of Oxford Wellcome Centre for Human Genetics	Environmental impacts associated with the manufacturing of personalised medicines: social and ethical issues
University of Oxford Wellcome Centre for Ethics and Humanities	Scoping Social Biases in AI Driven Precision Medicine Manufacturing
UCL Science & Technology Studies University of Vienna Political Science University of Oxford HeLEX Centre	Feasibility of novel, relevant ethical legal and social implications (ELSI) research on key ethical issues of personalised medicine: responsible PM
UCL Science, Technology Engineering and Public Policy	Risk assessment of information management tools and digital infrastructures for advanced therapies manufacturing

International collaborations

The Hub has continued to grow its international exposure and visibility through a range of collaborative and dissemination activities. In addition to presentations at international conferences (>110), and the publication of >170 papers in leading journals (see Publications), several new international collaborations have been integral to the Hub:

a) Collaborations / secondments on Hub GC research

- *LGC-led collaboration with Birkbeck, U. Exeter, U. Lancaster, U. Leeds, U. Manchester, NIBSC, UCB Pharma (UK), NRC (Canada), and U. Pavia (Italy): Led to joint publication on higher order structure analysis reference protocols (Dalby, UCL)*

b) Collaborative grant proposals

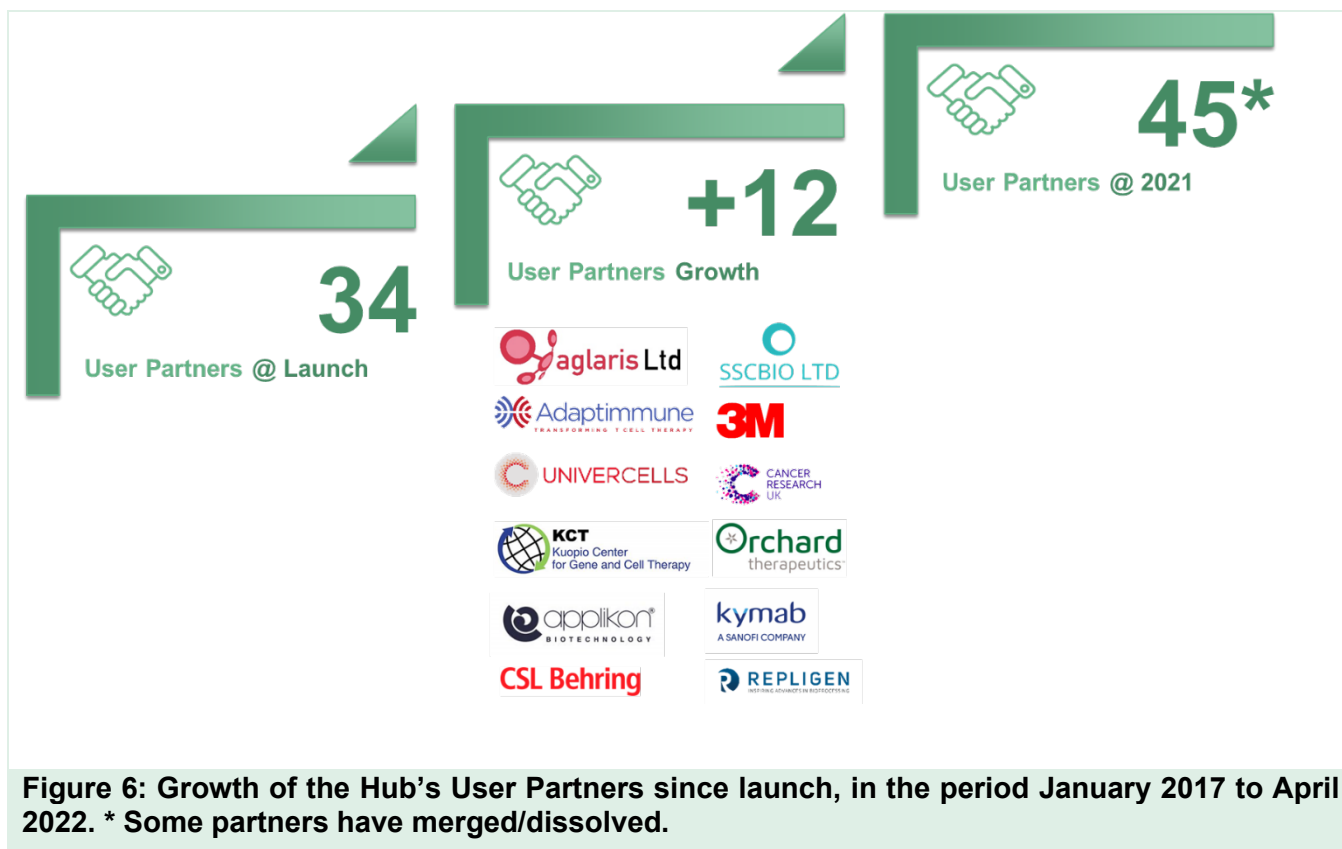
- *Partner on a collaborative EUR3.1M EU IMI grant (RealHOPE) led by RiSE in Sweden to track drug stability during patient handling, involving 12 European companies and 12 European Universities, research organisations, public bodies, hospitals or non-profit groups (Dalby, UCL).*
- *Partner on a collaborative EUR18.6M EU IMI grant (Inno4Vac) led by the European Vaccine Initiative, involving 12 European companies and 29 European Universities, research organisations, public bodies, or non-profit groups (Bracewell, UCL).*
- *Horizon 2020 Marie Skłodowska-Curie Innovative Training Network Grant on Continuous Downstream Processing of Bioproducts (CODOBIO) with 20 European universities and companies (EUR3.9M) (Farid, UCL).*
- *Partner on a collaborative EUR10.1M EU project focused on AI powered, Decentralized Production for Advanced Therapies in the Hospital (AIDPATH) involving 15 European universities, research centres and hospitals (Rafiq, Goldrick UCL).*

HUB USER ENGAGEMENT



Collaborator Engagement

Reflecting the vibrancy of the sector and interest in Hub activities, we continue to add members to the network, with Repligen and CSL Behring recent joiners. Now at 45 members, up from 34 at the launch, the Hub has a very active and engaged membership.



Mechanisms of engagement with collaborators (Figure 7) include:

- **User Steering Committees (USCs)** are bi-annual opportunities, usually in June and November, to present Hub research to stakeholders, and to learn about industry trends and sector news from invited keynote speakers.
- In 2021 keynote speakers included:
 - Prof Sam Turner, Chief Technology Officer from the High Value Manufacturing Catapult exploring opportunities from the digital sector for Industry 4.0 for biologics.
 - Prof Farzin Farzaneh from Kings College and ViroCell Biologics on lentiviral vectors small scale issues and large-scale challenges.
 - Prof Stephen Hart from UCL Great Ormond Street Institute of Child Health on RNA-based therapies for cystic fibrosis.
- The USCs have themed workshops, led by Hub Researchers or Principal Investigators designed to capture inputs and strategic directions from industrial collaborators. We have explored several new methods of obtaining different opinions, including interactive workspaces (Miro) and live online polls to elicit feedback.

- **Specialist Working Groups (SWGs)** provide anchor events for dialogue on five specific research themes within the Grand Challenges:
 - [ATMP Manufacture](#)
 - [Regulation, Reimbursement and Policy](#)
 - [Formulation and Analytics](#)
 - [Digital Decisional Tools](#)
 - [Cell-free Synthesis](#)
- Each SWG meets bi-annually, usually April / May and October to present research updates, and foster discussion and strategic planning between academia and industry. The SWGs remained online in 2021, awaiting a stable relaxation of restrictions. Guest speakers during 2021 SWG events included:
 - Claire Roddie, Co-Director of the UCL CAR T Programme at UCL Cancer Institute – Novel CD19 CAR T therapy.
 - Nicola Sherborne, Supplier Relationship Manager at AZ – Gearing up AZ’s Capacity Network and Supply Chains for Pandemic Response.
 - Jade Tuck, CPI / National Biologics Manufacturing Centre – mRNA synthesis and associated analytical challenges.
 - List of 2021 Guest Presenter Organisations: AstraZeneca, Centre for Process Innovation, FujiFilm Diosynth Biotechnologies, Ipsen, Kuopio Centre for Cell and Gene Therapy (KCT), Kymab-Sanofi, Redistributed Manufacturing in Health Network (RiHN), UCL Cancer Institute, University of Kent School of Biosciences, University of Twente Technical Medical Centre.

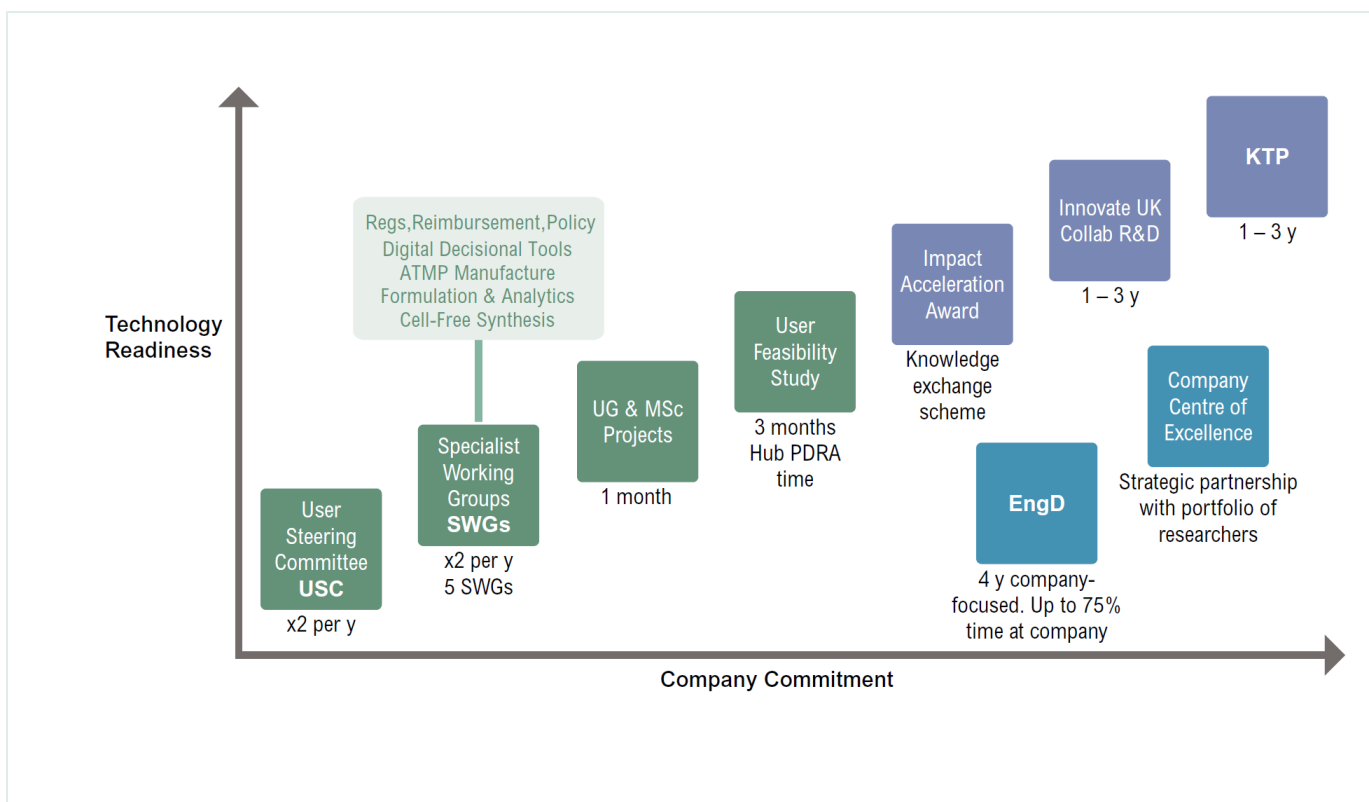


Figure 7: Mechanisms through which Users can engage with the Hub.



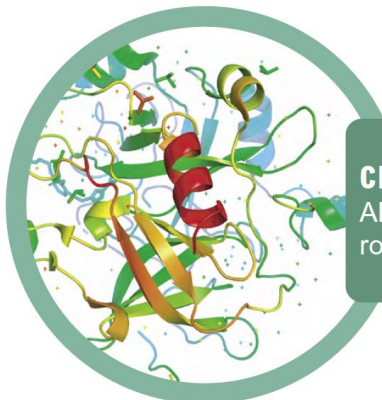
DIGITAL DECISIONAL TOOLS:

Optimising cost of goods, supply chain logistics, big data analytics and digital twins



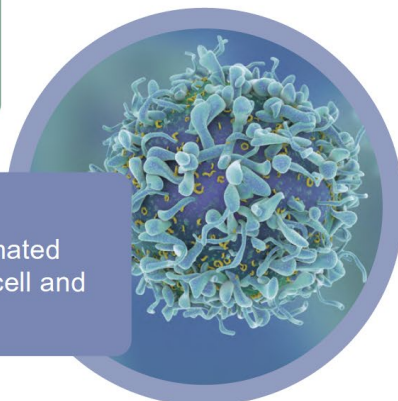
REGS, REIMBURSEMENT & POLICY:

Stakeholder mapping on regulatory pathways, reimbursement strategies for affordability, innovation policy



CELL-FREE SYNTHESIS:

Alternative, simplified manufacturing route to stratified medicinal proteins



ATMP MANUFACTURE:

Developing robust and automated manufacturing platforms for cell and gene therapies



FORMULATION AND ANALYTICS:

Creating advanced tools for product characterisation and digital formulation design

Figure 8: Specialist Working Groups (SWGs) of the Hub adapted to align with Phase II of the Hub with greater emphasis on digitalisation, policy, viral vectors and analytics

User Feasibility Studies: Enhancing Knowledge Exchange

The **user feasibility studies** continue to be a popular and successful mechanism, enabling users to examine new topics. Including up to 3 month of a Hub Researcher's time, spread over a period up to 12 months, the studies will test or demonstrate research techniques generated by the Hub in a company or user context. Typically, users provide industry supervision, and access to required materials, equipment or data. Enabling users to dip into new techniques, generate decisional models or even provide data to support government business cases, the annual call generates strong interest from the users. Outputs from the studies are relayed to the wider Hub community at SWG events, with many generating papers.

The application process for the user feasibility studies is very straightforward, with a 3 page application form for the work plan, deliverables and finance. Applications should be developed by the user organisation(s) in collaboration with the Hub Researchers. The award is a one-stage process (see <http://tinyurl.com/yc4zc8ca>) with a review of applications by the Translation & Impact Committee with ratification by the Advisory Board. The deadline for submissions in the next round is Wednesday 5 October 2022, with successful proposals announced late in November 2022.

Current User Feasibility Studies initiated in 2021 and 2022 are listed below in Table 3, demonstrating a wide variety of topics, from CAR-T and viral vector production methods, through digital decisional tool modelling for mMRA, cell therapies and viral vector processing, to advanced analytical techniques and novel formulation methods.

Table 3: List of new User Feasibility Studies supported within the Hub in across 2021 and 2022

Company Lead(s) & HEI partner	Topic
Albumedix University College London	Innovation in viral vector formulation using recombinant albumin
Autolus University College London, Imperial College London, University of Warwick	Techno-economic analysis and supply chain optimisation for the assessment of the "fresh-in/cryo-out" business model under uncertainty
Cell and Gene Therapy Catapult University of Manchester, University College London	Development of advanced process control approaches for the improved characterisation and optimisation of iPSC therapy manufacturing processes
Lonza University College London	Technical evaluation of the Lonza Cocoon platform for non-viral CAR-T production
NIBSC University College London	Raman spectroscopy of extracellular vesicles and lentiviral vectors
Pharmaron UK University College London	Adeno-associated vector formulation strategies
Univercells University College London	Economic evaluation of integrated mRNA vaccine platforms
Univercells (2) University College London	Economic evaluation of scalable and adherent cell culture platforms for the manufacture of viral vectors

User Feedback on Hub Impact

The positive impact of the user feasibility studies has been captured in these example testimonies from Oxford Biomedica / BIA and from Albumedix, the former demonstrating the impact on the national agenda, the latter a potential alternative to lyophilisation as a means of preserving biologics.

Impact Case Study: BioIndustry Association & Oxford Biomedica

Economic analysis to investigate the consequences of switching to scalable GMP processes for viral vectors on drug development lifecycle costs

“Viral vector gene therapy is a rapidly expanding treatment modality. In 2018, two organisations representing the UK biopharmaceutical sector, the BioIndustry Association (BIA) and the Medicines Manufacturing in Partnership (MMIP) reported that a number of UK gene therapy products in development had switched to overseas manufacture at the clinical stage. And once this had occurred, it was unlikely that commercial manufacture would return to the UK as the product would remain offshore in the same country as the clinical manufacturing. A need for more early-stage viral vector facilities within the UK was identified as a means of avoiding this product drain, anchoring the value added in the UK.

The BIA and Oxford Biomedica, a leading gene therapy company, identified that evidence to support the demand for additional viral vector facilities could be obtained through a Future Targeted Healthcare Manufacturing Hub’s feasibility study. By developing cost of goods (COGs) and process change models for gene therapy, it was demonstrated that by selecting a development pathway such that processes that can be scaled easily as the product transitions from preclinical to first-in-human and onto late-stage clinical trials and commercialisation, the overall profitability for the product is much improved.

Supporting the national agenda. Insights from the study were used as part of the BioIndustry Association’s business case to the UK Government, “Making a case for a UK Strategy for the Manufacture of GMP Viral Vectors,” to demonstrate how a UK-based supply chain can meet clinical and commercial demand and can collectively enhance its global in the ATMP manufacturing space. The BIA’s advocacy ultimately resulted in the MRC / LifeArc and BBSRC partnership which has created an £18M fund to promote clinical scale development through the establishment of Gene Therapy Innovation Hubs, a significant boost to the UK biopharmaceutical industry. The three hubs are at:

- The University of Sheffield Gene Therapy Innovation Manufacturing Centre (GTIMC)
- NHS Blood and Transplant Gene Therapy Hub at Filton
- The King’s College / Royal Free / UCL Gene Therapy Hub.

Promoting research partnerships. The quality of this high-impact research and the relationship built between UCL and Oxford Biomedica contributed to the founding of the BBSRC Collaborative Training Partnership in Advanced Bioscience of Viral Products (ABViP) in collaboration with the University of Oxford. This £4.5M doctoral training programme will see 24 students funded over 3 years, promoting both vital research in the gene therapy space and developing the next generation of researchers for this vital industry.”



James Miskin
Chief Technology Officer
Oxford Biomedica.



Netty England
BIA MAC

Impact Case Study: Albumedix*Formulating recombinant human albumin (rHA) as nanoparticle scaffolds and assessing the potential for drug delivery*

“Albumedix took the opportunity offered by the Future Targeted Healthcare Manufacturing Hub to assess how Hub tools could be applied to Albumedix’ products and challenges. Albumedix is a manufacturer of recombinant albumin that enables the effective formulation of otherwise hard-to-stabilize drugs, cell and gene therapies and vaccines as well as a media component for cell culture. Albumedix are investigating the use of protein drying technologies as a means of studying the stability of albumin. In the User Feasibility Study (UFS), Albumedix and Nottingham University used alcohol dehydration in a microfluidics system to generate albumin microparticles. These microparticles of Albumedix’ recombinant albumin products (Prime and Elite) were then characterised against lyophilised albumin.

Lyophilisation is frequently used in the biopharma industry as a means of prolonging shelf life and removing the need for cold supply chains. However, lyophilisation is both time-consuming, with some cycles taking multiple days, and is very energy intensive. The UFS was successful in showing that microparticles of Prime and Elite albumin could be formed using the novel alcohol dehydration method and that they had a similar stability to those formed from lyophilised protein powder. Further, the particles formed by alcohol dehydration were able to be reconstituted very rapidly, a critical property when delivering therapeutics or vaccines to patients. These particles were also granular and easy to handle compared to lyophilised powders which can be difficult to control and are prone to static effects. These findings indicate that alcohol dehydration has potential to be an alternative to lyophilisation for protein processing and storage.

The work in the UFS was sufficiently interesting for Albumedix for it to be progressed in a joint PhD programme between Nottingham, UCL and Albumedix. This included a long-term stability study of the albumin particles which followed aggregation formation by Dynamic Light Scattering, Size Exclusion Chromatography and UV Absorbance as well as MS analysis for protein modifications, some of which was performed in Albumedix. For the wider biopharma industry, the UFS demonstrates a rapid, sustainable method of preserving antibodies, vaccines and other biologics.”



Phil Morton
Chief Technology Officer
Albumedix

Wider Engagement and Benefits

Recent examples of benefits to collaborators reaching beyond traditional dissemination methods include:

- **Academics transitioning to industry** – Hub Researchers joining SMEs and co-founding start-ups: Rinri Therapeutics, Umabs Therapeutics. Hub Investigators secondment: Safi Biosolutions
- **PhDs and EngDs** aligned to the Hub mission and building on Hub outputs – 66 graduated to date from Emergent Macromolecular Therapies (EMT), and connections with the continuing doctoral training centres for Bioprocess Engineering Leadership (BEL), and Advanced Bioscience of Viral Products (ABViP).
- **MBI® CPD modular courses** – in 2021 support in the creation of 2 new MBI® modules contributing to continuing professional development for industrial professionals: “Advanced Data Analytics for Biopharmaceutical Optimisation” led by Stephen Goldrick and “Smart Digitalisation Decisions in Bioprocess Development and Manufacturing” led by Duygu Dikicioglu that each attracted 20 delegates.
- **New taught MSc** launched in 2020 in Manufacture & Commercialisation of Stem Cell and Gene Therapies (with Industry Steering Committee featuring many Hub members) to address the skills gap in this emerging sector. 2020 and 2021 saw healthy intakes with Hub research embedded via new workshop and lecture on ATMP process economics
- **Knowledge Transfer Partnerships (KTP)** - Hub activities have led to several KTP and knowledge exchange projects to ensure advances in methods are translated effectively into the user setting. These include KTPs with Sartorius Stedim UK to develop a new bioreactor vessel for adherent and suspension cell culture, with Biovault Technical to develop a scalable and consistent bioprocess for umbilical cord tissue (UCT) human stem cell production, with Perspectum Diagnostics Ltd to develop health economics analysis for a clinical diagnostic pathway for liver disease, with Aber Instruments to develop a biocapacitance analytical approach for cell therapies and with the Royal Free Hospital on cost of goods for bioartificial liver machine commercialisation.
- **Technology showcases** – The Cell and Gene Therapy Technology Showcase, online, featuring bioreactor platform technologies from Lonza, Sartorius, Repligen and Pall (April 2022).
- **Webinars** – “We must improve accessibility and affordability of biologics through innovation”, with Dr Jorg Thommes, EVP of Pharmaceutical Sciences and Operations, Repertoire Immune Medicine (February 2022),

DEVELOPING THE HUB TEAM

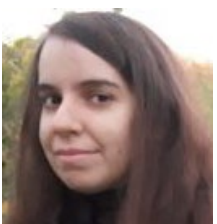


Hub Researcher Perspectives



“Coming from an academic background, the Hub has helped me to gain exposure to industry and apply my research in new ways. I have had the opportunity to meet and discuss my research with a number of industrial experts, which helped me shape and refine my decision-support models, and address industrially relevant questions in biomanufacturing. Compared with a conventional post-doctoral position, the level of exposure to industry is quite unique. Since joining the team, I have gained a better understanding of how different areas of research can come together to tackle complex problems. In turn, this has given me a new perspective on driving my own research forward.”

Dr Christos Stamatidis, Biochemical Engineer and Process-Economic Modeller, University College London



“Being part of the Hub has helped me expand my knowledge through other research fields that I have never been familiar with. This includes applying my own expertise but also learning other techniques that are new to me. Another of the things that has been interesting for me so far are the collaboration with industry, and the types of interaction and involvement with industrial research. And more engagement with academia and industry through events, specialist working groups and project team meetings. I think the training opportunities feel much wider than a traditional post-doc role would give, and this will help build my future as an independent researcher.”

Dr Raquel Fernández-García, Bioengineering Scientist and Pharmacist, University of Nottingham



“Since being part of the Hub, I have really enjoyed the opportunity to apply my expertise to this field and develop my skills in a new area. It has been so interesting to work in interdisciplinary research and development in such a challenging area, and towards new technologies that industry will want to use. Mixing with a number of people from academia, industry and other organisations has helped grow my understanding of the kind of solutions that the industry is looking for. I have found it very useful and helpful connecting with specialists from different backgrounds across the team. Plus the people are great and it is a nice team to be a part of.”

Dr Igor Andreyev, Biophysical and Mathematical Development Scientist, University College London

Innovative Working Practices

Supporting the success of the Hub's dedicated researchers, as a team and as individuals, is integral to the success of the Hub itself. The Hub Researcher team drives the day-to-day connectedness across the academic Hub and Spoke network and are at the center of the engagements with the Hub's industrial community. Thus, we have created an environment to give Hub Researchers a voice for leadership, opportunities for teaching, training and learning from each other, exposure to industry and the wider sector.

Collaborative working

The Hub Specialist Working Groups (SWGs), and Hub Researcher-led interactive technical workshops at User Steering Committees act as a forum for Hub Researchers to engage with industry, and wider stakeholders, to gain critical feedback on their research direction and impact, and also to work on team-oriented challenges. In addition to the SWGs, PDRAs are also encouraged to engage each other, and the wider community via challenge-led teams. For example, an AAV manufacturing challenge team was assembled to develop in-house strategies for AAV serotype manufacturing and analytics. This provides a platform for bioprocess research, as well as materials for subsequent development of analytics and formulations. This has now grown into a viral vector taskforce, which meets monthly to bring together PDRAs, PhDs and technical staff across the viral vector manufacturing, analytics and formulation.

Career progression

Thirteen Hub PDRA Researchers have now progressed into higher roles in academia or industry. In 2021 Dr Yang Yang took up lecturer position in Big Data in Digital Manufacturing at Brunel University's Department of Chemical Engineering. Dr Mariam Shariatzadeh moved on to a senior scientist role at Rinri Therapeutics, a biotechnology company developing first-in-class cell therapies to restore hearing. Dr Hongyu Zhang has co-founded a start-up company Umabs Therapeutics, applying big data and artificial intelligence in drug discovery and development.

These high-achieving roles reflect the industry and academic demand for researchers trained in the sector, and also the high-regard that potential employers have for the Hub. A key feature in driving this, has been the training opportunities that the Hub Researchers have had for widening their skillbase. Not only are they exposed to regular research updates from each other, but they have also been actively engaged in collaborations with each other, facilitated by training workshops to forge multi-disciplinary learning, such as in the use of the Pilot Plant, and also in Policy.

Graduate student training within the Hub

Alongside the Hub Researchers, a total of 114 manufacturing and process specialist students have benefitted from training to PhD/EngD level in the Hub's new ways of working required for targeted medicines, and most will seek jobs in the sector. Many of these have been co-supervised by the Hub Researcher team, providing them with further skills in leadership through research supervision and project management. The students were funded as 46 EPSRC CDT in Emergent Macromolecular Therapies (EMT) PhDs, 52 EPSRC in Bioprocess Leadership EngDs, and the remainder from DTP, UCL-scholarships and overseas scholarships. Of these, 52 PhD/EngD students have graduated so far, fully trained in Hub methods and innovations, and 48% have gone into Bioindustry roles, while 24% have taken up PostDoctoral Research posts, 8% became Teaching Fellows, and the remaining 20% went into other sector-related industries. Over 70% of the EPSRC CDT in EMT PhD students were based at external institutions, bringing these collaborating universities into the Hub's extended research community. All Y1 and Y3 students have presented posters and selected final year students have presented orally at the bi-annual Hub User Steering Committee meetings.

Equality, Diversity and Inclusion (ED&I)

The Hub follows UCL's policy on ED&I via HR policy and are informed by guidelines from the Faculty of Engineering ED&I committee. The Directors work closely with ED&I Deputy Head, Network Envoy and the Faculty Lead for Black and Minority Ethnic (BME) Student Attainment from within UCL Biochemical Engineering. The Department of Biochemical Engineering that hosts the Hub, is highly pro-active in realising the goals of ED&I, and has taken the lead at UCL on achievements within the Athena Swan scheme.

Crucially, all PIs across the Hub and Spokes have been required to undertake unconscious bias training prior to the advertisement and recruitment of any new Hub Researchers. The Hub Management Board manages and tracks ED&I goals and performance, with data from HR (compliant with GDPR). For Hub-aligned PhD/EngD students this is managed via respective CDT management committees, as well as the Dept of Biochemical Engineering Doctoral Committee, and reported to the Hub Management Board. The Hub ED&I action plan is reviewed and updated annually, with feedback from the Advisory Board. Goals to put in place monitoring, unconscious bias training, and ensure diversity at committees, panels and events, have already been met, and updated in line with the UCL and Faculty of Engineering ED&I strategies.

Key future goals include:

- Solicit a direct review of Hub ED&I strategy and goals by the UCL ED&I committee.
- Guaranteed interviews for applicants from under-represented groups.
- Update of web-based materials and communications to ensure that images and messages are inclusive of the diversity of research staff, students and industrial sponsors.
- Foster linkages with established UCL ED&I communities: RaceMatters@UCL, LGBT+Allies, Out@UCL, Enable@UCL and the network of UCL AthenaSWAN departmental committees.

HUB DIRECTORY



Hub & Spoke Academic Team

An overview of the current team, based across six leading universities and eight university schools and departments

THE HUB @ UCL

UCL DEPARTMENT OF BIOCHEMICAL ENGINEERING

CELL-FREE SYNTHESIS, CELL THERAPY AND FORMULATION EXPERIMENTAL RESEARCH, DIGITAL DECISIONAL TOOLS



Professor Nigel Titchener-Hooker

Position: Principal Investigator, Hub Strategy Director, Professor of Biochemical Engineering, Dean of Faculty of Engineering Sciences

Expertise: Creation of whole bioprocess models and the use of these to gain process insights and understanding

Webpage: <http://iris.ucl.ac.uk/iris/browse/profile?upi=NJTIT16>

DECISIONAL TOOLS RESEARCH



Professor Suzanne Farid

Position: Hub Co-Director, Professor of Bioprocess Systems Engineering

Expertise: Bioprocess Decisional Tools, Bioprocess Economics, Drug Development Cost Modelling, Capacity planning, Portfolio Management, Risk Analysis, Multi-Criteria Decision-Making, Multi-Objective Simulation & Optimisation, Chemometrics

Webpage: <http://iris.ucl.ac.uk/iris/browse/profile?upi=SFARI53>

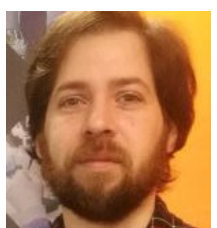


Dr Stephen Goldrick

Position: Hub Co-Investigator (2020-), Lecturer in Digital Bioprocess Engineering

Expertise: Advanced Data Analytics, Mathematical Modelling, Machine learning, Process Analytical Technology, Digital Twin

Webpage: <https://iris.ucl.ac.uk/iris/browse/profile?upi=SGOLD17>



Dr Christos Stamatis

Position: Hub Researcher

Training: Chemical Engineering (MEng), Biochemical Engineering (MSc, EngD)

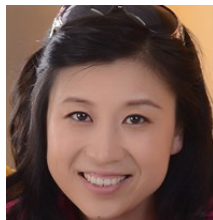
Expertise: Decisional tools, Process economics for mAbs and bispecifics, Chromatography process development

**Dr Nivedhitha Swaminathan**

Position: Hub Researcher (from July 2022)

Training: Industrial Biotechnology (Bachelors), Bioprocess Engineering (PhD)

Expertise: Process analytical technology, mathematical modelling, simulation, process optimisation and process control

**Dr Yang Yang**

Position: Former Hub Researcher (to 2021), Next Destination: Brunel University

Training: Computer Science (BSc, MSc), Chemical Engineering (PhD)

Expertise: Bioprocess modelling and simulation, multivariate data analysis for DSP, decisional tool development

CELL-FREE SYNTHESIS EXPERIMENTAL RESEARCH**Professor Daniel Bracewell**

Position: Hub Co-Investigator, Professor of Bioprocess Analysis

Expertise: Bioprocess analysis; Speed and capabilities of the analytical techniques used

Webpage: <https://iris.ucl.ac.uk/iris/browse/profile?upi=DGBRA75>

**Dr Beatrice Melinek**

Position: Hub Researcher

Training: MEng in Chemical Engineering, EngD in Biochemical Engineering

Expertise: Cell-free synthesis of biomolecules. Additionally, viral vaccine/vector purification and process simulation

FORMULATION EXPERIMENTAL RESEARCH



Professor Paul Dalby

Position: Hub Co-Director, Professor of Biochemical Engineering and Biotechnology

Expertise: Routes to improve the stability and activity of biocatalytic enzymes and therapeutic proteins, for ease of manufacture, formulation and delivery to patients

Webpage: <https://iris.ucl.ac.uk/iris/browse/profile?upi=PADAL59>

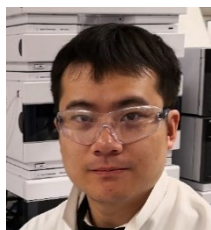


Dr Samir Aoudjane

Position: Hub Researcher

Training: Genetics (BSc), Experimental Medicine (MSc), Biophysics (PhD)

Expertise: Optical analysis systems, protein and nucleic acid molecular biophysics, drug development



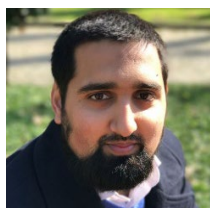
Dr Hongyu Zhang

Position: Former Hub Researcher (to January 2021). Next Destination: Umabs Therapeutics

Training: Protein aggregation specialist

Expertise: Chromatography, time-resolved fluorescence spectroscopy

CELL THERAPY EXPERIMENTAL RESEARCH



Dr Qasim Rafiq

Position: Hub Co-Investigator, Associate Professor in Bioprocessing of Regenerative, Cellular and Gene Therapy

Expertise: Bioprocessing and translation of advanced cell and gene therapies from the lab-scale to clinical and commercial scales

Webpage: <https://iris.ucl.ac.uk/iris/browse/profile?upi=QARAF73>



Dr Nourredine Himoudi

Position: Hub Researcher

Training: MSc Biotechnology; PhD Immunology, immunotherapy, GMP and ATIMPs manufacture management for cancer patients

Expertise: Scale up, validation, manufacture and GMP production management of gene modified T cells (TCR and Chimeric Antigen Receptors) for cancer immunotherapy.



Professor Nicolas Szita

Position: Professor of Bioprocess Microfluidics

Expertise: Translation of bioprocessing concepts into microfluidic systems (or Lab-on-a-chip systems); Use of advanced microfabrication techniques for polymers (rapid prototyping), glass and silicon

Webpage: <https://iris.ucl.ac.uk/iris/browse/profile?upi=NSZIT68>



Dr Igor Andreyev

Position: Hub Researcher

Training: MSc Physics, PhD Physical and Mathematical Sciences, postgraduate MSc Laser Technologies and in Biotechnology

Expertise: Biophysics, laser and optical instrumentation, AFM, Raman, advanced statistics, microsystem engineering and microfluidics, nanotechnology

UCL DEPARTMENT OF APPLIED HEALTH RESEARCH (DAHR)

HEALTH ECONOMICS RESEARCH



Professor Paula Lorgelly

Position: former Hub Co-Investigator (to May 2022), Next Destination: University of Auckland, NZ

Expertise: Economic evaluation particularly in the areas of oncology, genomics and precision medicine; Outcome measurement including comparing different Health Related Quality of Life instruments, eliciting patient preferences and outcome-based payment or incentive schemes

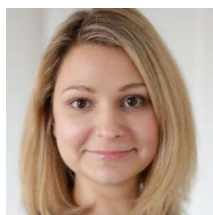


Ms Nishma Patel

Position: Hub Researcher

Training: Health Economist

Expertise: Economic evaluation alongside clinical trials, effects of specialist cancer services, health technology adoption

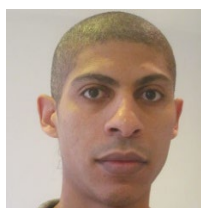


Dr Irina Brass

Position: Hub Co-Investigator, Associate Professor in Regulation, Innovation and Public Policy

Expertise: Regulation of emerging technologies; managing emerging risks and uncertainty of disruptive innovation; public policy and governance

Webpage: <http://www.ucl.ac.uk/steapp/people/brass>



Dr Edison Bicudo

Position: Hub Researcher

Training: PhD International Politics, Master's in Geography, Bachelor's in Social Sciences

Expertise: Social and geographical implications of biomedical technologies, e.g. bioinformatics, neuroimaging software, bioprinting

IMPERIAL COLLEGE LONDON DEPARTMENT OF CHEMICAL ENGINEERING

SUPPLY CHAIN OPTIMISATION RESEARCH

**Professor Nilay Shah**

Position: Hub Co-Investigator, Head of Department of Chemical Engineering, Professor of Process Systems Engineering

Expertise: Supply chain design and optimisation; Process synthesis and development for fine chemicals, pharmaceutical and biochemical processes; Mathematical techniques to assess and improve process safety

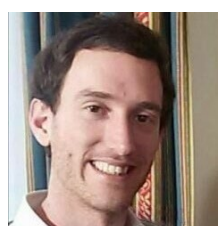
Webpage: <http://www.imperial.ac.uk/people/n.shah>

**Dr Maria Papathanasiou**

Position: Hub Co-Investigator (2020-), Lecturer in Chemical Engineering

Expertise: Decisional and computational tools, Process modelling, simulation and optimisation, Bioprocess modelling (bioreactors & separation processes)

Webpage: <https://www.imperial.ac.uk/people/maria.papathanasiou11>

**Dr Andrea Bernardi**

Position: Hub Researcher

Training: Chemical Engineer, PhD

Expertise: Computational tools, Model-identification and parameter estimation, Process design and optimization, Supply chain optimization, Life cycle assessment

LOUGHBOROUGH UNIVERSITY SCHOOL OF MECH, ELEC & MANUFACTURING ENGINEERING

CELL THERAPY FIRST-PRINCIPLES MODELLING RESEARCH



Professor Robert Thomas

Position: Hub Co-Investigator, Professor of Manufacturing for Cell and Gene Therapies

Expertise: Production systems for cell based products; Translation to commercial manufacture and clinical use; Automated and scaled production; Measurement systems for process control and quality release; defining indicators of cell quality.

Webpage: <http://www.lboro.ac.uk/departments/meme/staff/robert-thomas/>



Dr Maryam Shariatzadeh

Position: Former Hub Researcher (to Nov 2021). Next Destination: Rinri Therapeutics

Training: PharmD, Chemical Engineering, PhD

Expertise: T cell manufacturing; Automated and scaled production; Cell therapies; Stem cell manufacturing; Regenerative medicine

UNIVERSITY OF MANCHESTER DEPARTMENT OF ELECTRONIC & ELECTRICAL ENGINEERING

MONITORING AND CONTROL RESEARCH



Professor Barry Lennox

Position: Hub Co-Investigator, Professor of Applied Control

Expertise: Robotics for use in Nuclear Engineering Decommissioning, Leakage and blockage detection in pipelines; Multivariate statistical process control; Model predictive control;

Control loop monitoring; Monitoring and control of batch processes.

Webpage: <https://www.research.manchester.ac.uk/portal/barry.lennox.html>



Dr Carlos Alberto Duran Villalobos

Position: Hub Researcher

Training: Electronics Engineer/ MSc Digital Signal Processing/ PhD Process Control

Expertise: Process Control, Multivariate Analysis, Adaptive Control, Data-based Models

UNIVERSITY OF NOTTINGHAM SCHOOL OF PHARMACY

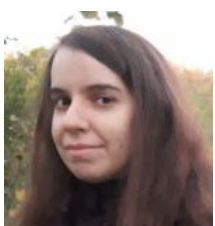
NANOENCAPSULATION FORMULATION RESEARCH

**Professor Jonathan Aylott**

Position: Hub Co-Investigator, Professor in Analytical Bioscience

Expertise: Design, development and implementation of miniaturized analytical devices

Webpage: <https://www.nottingham.ac.uk/Pharmacy/People/jon.aylott>

**Dr Raquel Fernandez-Garcia**

Position: Hub Researcher

Training: MPharm, PhD

Expertise: Engineering and characterisation of novel formulations

UNIVERSITY OF WARWICK, WARWICK BUSINESS SCHOOL

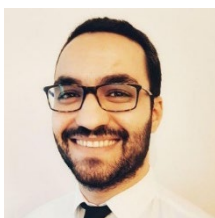
PRODUCTION PLANNING RESEARCH

**Professor Juergen Branke**

Position: Hub Co-Investigator, Professor of Operational Research & Systems

Expertise: Optimisation under Uncertainty, Multi-Objective Optimisation, Simulation-based Optimisation

Webpage: <http://www.wbs.ac.uk/about/person/juergen-branke/>

**Dr Siamak Naderi**

Position: Hub Researcher

Training: Industrial Engineering (BSc, MSc, PhD)

Expertise: Operations and Supply Chain Management,

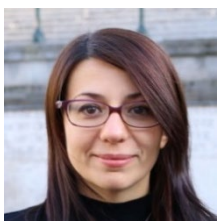
Large-Scale Optimisation, Operations Research, Business Analytics

OPERATIONS & OUTREACH TEAM



Dr Eleanor Bonnist

Former Project Manager (to Aug 2022) at UCL Biochemical Engineering.
Next Destination: The Francis Crick Institute



Miss Laura Pascual Buffone

Research Finance Officer
UCL Biochemical Engineering



Dr Penny Carmichael

Former Biomanufacturing Policy Adviser (to July 2022) at UCL STEaPP, Policy Impact Unit.
Next Destination: Ofgem



Dr Vaughan Thomas

Hub Outreach Consultant
Tillingbourne Consulting

FORMER TEAM MEMBERS

And next destination(s) after the Hub

Former Hub Researchers: Dr Veeren Chauhan (University of Nottingham), Dr Adam Collins (Mettler Toledo International), Dr Giovanni De Grandis (Norwegian University of Science and Technology), Dr Xin Fei (University of Bristol, University of Edinburgh), Dr Elvan Gökalp (Warwick University, University of Bath), Dr Shimaz Hashimdeen (LGC), Dr Olotu Ogonah (Oxford Biomedica), Dr Theano Panagopoulou (Achilles Therapeutics), Dr Maria Papathanasiou (Imperial College London), Dr Mariam Shariatzadeh (Rinri Therapeutics), Dr Xiaonan Wang (National University of Singapore), Dr Yang Yang (Brunel University), Dr Hongyu Zhang (Umabs Therapeutics)

Former Hub Investigators: Prof Paula Lorgelly (The University of Auckland), Prof Steve Morris (University of Cambridge), Prof Arthur Petersen? (University College London), Dr Ivan Wall (Aston University, University of Birmingham), Dr Farlan Veraitch (OriBiotech)

Hub User Partners

Partnering companies and organisations, April 2022

Companies

	3M
	Adaptimmune Therapeutics
	Aglaris
	Albumedix
	Applikon Biotechnology (Getinge)
	AstraZeneca
	Autolus
	BIA Separations (Sartorius)
	Biologic B
	BioPharm Services
	CSL Behring
	deltaDOT
	Eli Lilly
	Fujifilm Diosynth Biotechnologies
	GSK



Ipsen



Kymab (Sanofi)



Kuopio Centre for Cell and Gene Therapy



Lonza



Orchard Therapeutics



Oxford BioMedica



Pall



Perceptive Engineering



Pharmaron



Purify (Cytiva)



Purolite



ReNeuron



Repligen



Sartorius



SSC Bio



Sutro BioPharma



Tillingbourne Consulting



TrakCel



Univercells



West Pharmaceutical Services



Wyatt Technology

Industry/Govt Associations and Charities



Association of the British Pharmaceutical Industry



BioIndustry Association



Cancer Research UK



Knowledge Transfer Network



LGC



Medicines Manufacturing Industry Partnership



National Institute for Biological Standards & Control

Translational Spokes



Cell and Gene Therapy Catapult



Centre for Process Innovation/ National Biologics Manufacturing Centre

EVENTS AND PUBLICATIONS



Hub Events 2021

The Hub events are listed below. These invite members of the Hub's partnering companies and organisations to hear updates on the progress of the research and to input and interact with the project.

16-17 February	Mid Term Review with EPSRC and independently-appointed panel
30 March	Translation and Impact Committee
16 March	Cell-Free Synthesis Specialist Working Group
18 March	Formulation Specialist Working Group
25 March	ATMP Manufacture Specialist Working Group
16 April	Healthcare Regulation, Reimbursement and Policy Specialist Working Group
18 May	Digital Decisional Tools Specialist Working Group
2 June	User Steering Committee Meeting
3 June	Advisory Board Meeting
26 June	Regulation of ATMPs Manufactured at the Point of Care, with the MHRA & Lonza
9 September	The Ethics of Manufacturing Personalised Medicines
5 October	Cell-Free Synthesis Specialist Working Group
8 October	Formulation Specialist Working Group
22 October	Healthcare Regulation, Reimbursement and Policy Specialist Working Group
27 October	Digital Decisional Tools Specialist Working Group
10 November	User Steering Committee Meeting
12 November	Advisory Board Meeting
2 December	ATMP Manufacture Specialist Working Group

Selected Hub Publications

Journal Articles

Underlining denotes members of the dedicated Hub Researcher team

2022

Machine learning application in personalised lung cancer recurrence and survivability prediction

Yang Y, Xu L, Sun L, Zhang P, Farid SS

Computational and Structural Biotechnology Journal, 2022, **20**, 1811-1820, doi: 10.1016/j.csbj.2022.03.035.

Data integrity within the biopharmaceutical sector in the era of Industry 4.0

Alosert H, Savery J, Rheaume J, Cheeks M, Turner R, Spencer C, Farid SS, Goldrick, S

Biotechnology Journal, 2022, e2100609. doi:10.1002/biot.202100609

Development of a model to demonstrate the impact of National Institute of Health and Care Excellence cost-effectiveness assessment on health utility for targeted medicines

Gallacher D, Stallard N, Kimani P, Gokalp E, Branke J

Health Economics, 2022, **31** (2), 417-430, doi: 10.1002/hec.4459

Systematic design, generation, and application of synthetic datasets for flow cytometry

Cheung M, Campbell JJ, Thomas RJ, Braybrook J, Petzing J

PDA Journal of Pharmaceutical Science and Technology, 2022, **76** (1), doi: 10.5731/pdajpst.2021.012659

Protein engineering and HDX identify structural regions of G-CSF critical to its stability and aggregation

Wood VE, Groves K, Wong LM, Kong L, Bird C, Wadhwa M, Quaglia M, Matejtschuck P, Dalby PA

Molecular Pharmaceutics, 2022, **19**(2), 616-629, doi: 10.1021/acs.molpharmaceut.1c00754

Assessment of intermediate storage and distribution nodes in personalised medicine

Bernardi A, Sarkis M, Triantafyllou N, Lakelin M, Shah N, Papathanasiou M M

Computers and Chemical Engineering, 2022, **157**, p. 107582, doi: 10.1016/j.compchemeng.2021.107582

2021**Multivariate batch to batch optimisation of fermentation processes to improve productivity**

Barton M, [Duran-Villalobos CA](#), Lennox B

Journal of Process Control, 2021, **108**, 148-156, doi:10.1016/J.JPROCONT.2021.11.007

Gold-oligonucleotide nanoconstructs engineered to detect conserved enteroviral nucleic acid sequences

Chauhan V, Aylott JW

Biosensors, 2021, **11** (7), 238, doi: 10.3390/bios11070238

Lipid reduction to improve clarification and filterability during primary recovery of intracellular products in yeast lysates using exogenous lipase

Bandyopadhyaha SK, Morris SA, Nesbeth DN, Bracewell DG

Journal of Chemical Technology and Biotechnology, 2021, **96** (11), 3166-3176, doi: 10.1002/jctb.6871

Current trends in flow cytometry automated data analysis software

Cheung M, Campbel JJ, Whitby L, Thomas RJ, Braybrook J, Petzing J

Cytometry Part A, 2021, **99** (10), 1007-1021, doi: 10.1002/cyto.a.24320

Application of a simple unstructured kinetic and cost of goods models to support T-cell therapy manufacture

[Shariatzadeh M](#), Lopes, AG, Glen, K, Sinclair, A, Thomas, R

Biotechnology Progress, 2021, btpr.3205, ISSN: 8756-7938. DOI: 10.1002/btpr.3205.

Accelerating product and process development through a model centric approach

Antonakoudis A, Kis Z, Kontoravdi K, Kotidis P, Papathanasiou MM, Shah N, Tomba E, Varsakelis C, von Stoch M

In *Quality by Design - An Indispensable Approach to Accelerate Biopharmaceutical Product Development*, Book chapter Editors: Campa, Khan, Publisher: Parenteral Drug Association, Inc., 2021, pp 285-338.

Stability modelling for biopharmaceutical process intermediates

Kis Z, Papathanasiou MM, Kotidis P, Antonakoudis T, Kontoravdi K, Shah N

in *Quality by Design - An Indispensable Approach to Accelerate Biopharmaceutical Product Development*, Editors: Campa, Khan, Publisher: Parenteral Drug Association, Inc, 2021, pp 200-225.

Assessment of intermediate storage and distribution nodes in personalised medicine

[Bernardi A](#), Papathanasiou M, Lakelin M, Shah N

Computer Aided Chemical Engineering. Vol. 50. Elsevier, 2021. 1997-2002.

DigiGlyc: A hybrid tool for reactive scheduling in cell culture systems

Kotidis P, Pappas I, Avraamidou S, Pistikopoulos EN, Kontoravdi C, Papathanasiou MM,
Computers & Chemical Engineering, 2021, **154**,107460, doi: 10.1016/j.compchemeng.2021.107460

Decision support tools for next-generation vaccines and advanced therapy medicinal products: present and future

Sarkis M, Bernardi A, Shah N, Papathanasiou MM
Current Opinion in Chemical Engineering, 2021,**32**, 100689, doi: 10.1016/j.coche.2021.100689

Decisional tool for cost of goods analysis of bioartificial liver devices for routine clinical use

Mendonça da Silva J, Stamatis C, Chalmers S-A, Erro E, Selden C, Farid SS
Cytotherapy, 2021, **23**(8), 683-693, doi:10.1016/j.jcyt.2021.04.006

End-to-end continuous bioprocessing: impact on facility design, cost of goods and cost of development for monoclonal antibodies.

Mahal H, Branton H, Farid SS
Biotechnology and Bioengineering, 2021, **118**(9),3468-3485, doi:10.1002/bit.27774

Gene therapy process change evaluation framework: Transient transfection and stable producer cell line comparison

Comisel RM, Kara B, Fiesser FH, Farid SS
Biochemical Engineering Journal, 2021, **176**,108202, doi:10.1016/j.bej.2021.108202

Lentiviral vector bioprocess economics for cell and gene therapy commercialization

Comisel RM, Kara B, Fiesser FH, Farid SS
Biochemical Engineering Journal, 2021, **167**, 107868, doi:10.1016/j.bej.2020.107868

A Common Framework for integrated and continuous biomanufacturing

Coffman J, Brower M, Connell-Crowley L, Deldari S, Farid SS, Horowski B, Patil U, Pollard D, Qadan M, Rose S, Schaefer E, Shultz J
Biotechnology and Bioengineering, 2021,**118** (4), 1735-1749, doi: 10.1002/bit.27690

Comparison of the pH- and thermally-induced fluctuations of a therapeutic antibody Fab fragment by molecular dynamics simulation

Zhang C, Codina N, Tang J, Yu H, Chakroun N, Kozielski F, Dalby PA
Computational and Structural Biotechnology Journal, 2021, **19**, 2726-2741.
doi:10.1016/j.csbj.2021.05.005

Machine learning reveals hidden stability code in protein native fluorescence

Zhang H, Yang Y, Zhang C, Farid SS, Dalby PA
Computational and Structural Biotechnology Journal, 2021, **19**,2750-2760,
doi:10.1016/j.csbj.2021.04.047

Reference Protocol to Assess Analytical Performance of Higher Order Structural Analysis

Measurements: Results from an Interlaboratory Comparison.

Groves K, Ashcroft AE, Cryar A, Sula, Wallace BA, Stocks BB, Burns C, Cooper-Shepherd D, De Lorenzi D, Rodriguez H, Zhang H, Ault JR, Ferguson J, Phillips JJ, Pacholarz K, Thalassinos K, Luckau L, Ashton L, Durrant O, Barran P, Dalby PA, Vicedo P, Colombo R, Davis R, Parakra R, Upton R, Hill S, Wood V, Soloviev S, Quaglia M,

Analytical Chemistry, 2021, **93**(26), 9041-9048. doi:10.1021/acs.analchem.0c04625

The UK's emerging regulatory framework for point-of-care manufacture: insights from a workshop on advanced therapies

Bicudo E, Brass I, Carmichael P, Farid S

Cell and Gene Therapy Insights, 2021, **7** (9), 1005-1015, doi:10.18609/cgti.2021.133

Lentiviral vectors for T cell engineering: Clinical applications, bioprocessing and future perspectives

Labbé RP, Vessillier S, Rafiq QA

Viruses, 2021, **13** (8), doi:10.3390/v13081528

Microfluidic Devices as Process Development Tools for Cellular Therapy Manufacturing

Aranda Hernandez J, Heuer C, Bahnemann J, Szita N

In *Advances in Biochemical Engineering/Biotechnology*, Springer Verlag, 2021, doi.org/10.1007/10_2021_169

Reactor Design for Continuous Monoclonal Antibody Precipitation Based Upon Micro-mixing

Martinez M, Mannall, G, Spitali M, Norrant EL, Bracewell, DG

Journal of Chemical Technology & Biotechnology, 2021, jctb.6652, doi:10.1002/jctb.6652

Advanced control strategies for bioprocess chromatography: Challenges and opportunities for intensified processes and next generation products

Armstrong A, Horry K, Cui T, Hulley M, Turner R, Farid SS, Goldrick S, Bracewell DG

Journal of Chromatography A, 2021, 1639. doi:10.1016/j.chroma.2021.461914

Analytics of host cell proteins (HCPs): lessons from biopharmaceutical mAb analysis for Gene therapy products

Bracewell DG, Smith V, Delahaye M, Smales CM

Current Opinion in Biotechnology, 2021, **71**, 98-104, doi:10.1016/j.copbio.2021.06.026

Enriching leukapheresis improves T cell activation and transduction efficiency during CAR T processing

Noaks, E, Peticone C, Kotsopoulou E, Bracewell DG

Molecular Therapy - Methods and Clinical Development, 2021, **20**, 675-687, doi:10.1016/j.omtm.2021.02.002

Design and development of a new ambr250® bioreactor vessel for improved cell and gene therapy applications

Rotondi M, Grace N, Betts J, Bargh N, Costariol E, Zoro B, Hewitt CJ, Nienow AW, Rafiq QA
Biotechnology Letters, 2021, **43**, 1103–1116, doi: 10.1007/s10529-021-03076-3

Escherichia Coli-Based Cell-Free Protein Synthesis for Iterative Design of Tandem-Core Virus-Like Particles

Colant N, Melinek B, Frank S, Rosenberg W, Bracewell DG
Vaccines, 2021, **9**(3), 193, doi: 10.3390/vaccines9030193

High-Throughput Process Development for the Chromatographic Purification of Viral Antigens

Jacob SI, Konstantinidis S, Bracewell DG

In: Vaccine Delivery Technology, Pfeifer BA, Hill A (eds), Methods in Molecular Biology, 2183 Humana, New York, NY, doi: 10.1007/978-1-0716-0795-4_9

Proof-of-concept analytical instrument for label-free optical de-convolution of protein species in a mixture

Hales J. E., Aoudjane S., Aeppli G., Dalby P. A.

Journal of Chromatography A, 2021, **1641**, 461968, doi: 10.1016/j.chroma.2021.461968

Solution structure of deglycosylated human IgG1 shows the role of CH2 glycans in its conformation

Spiteri V. A., Douth J., Rambo R. P., Gor J., Dalby P. A., Perkins S. J.

BioPhysical Journal, 2021, **200**, 1814-1834, doi: 10.1016/j.bpj.2021.02.038

Multivariate statistical data analysis of cell-free protein synthesis toward monitoring and control

Duran-Villalobos CA, Ogonah O, Melinek B, Bracewell DG, Hallam T, Lennox B

AIChE Journal, 2021, **67**:e17257, doi: 10.1002/aic.17257

Understanding cell culture dynamics: a tool for defining protocol parameters for improved processes and efficient manufacturing using human embryonic stem cells

Kusena J, Shariatzadeh M, Thomas R, Wilson S

Bioengineered, 2021, **12** (1), 979-996, doi: 10.1080/21655979.2021.1902696

The importance of cell culture parameter standardization: an assessment of the robustness of the 2102Ep reference cell line

Kusena J, Shariatzadeh M, Studd A, James JR, Thomas R, Wilson S

Bioengineered, 2021, **12**(1), 341-357, doi: 10.1080/21655979.2020.1870074

Emerging Challenges and Opportunities in Pharmaceutical Manufacturing and Distribution

Miriam Sarkis M, Bernardi A, Shah N, Papathanasiou MM

Processes, 2021, **9**(3), 457, doi: 10.3390/pr9030457

Conference Presentations

2022

Suzanne Farid

Conference Chair: Recovery of Biological Products XIX Conference

10-15 July 2022, Rome, Italy

Nigel Titchener-Hooker

Session Chair: Modeling Next Generation Supply Chains & Facilities: Envisaging the Challenges – Engineering the Solutions

Recovery of Biological Products XIX Conference

10-15 July 2022, Rome, Italy

Christos Stamatis

Decisional tools for successful commercialisation of cell and gene therapies: industrial case studies

Recovery of Biological Products XIX Conference

10-15 July 2022, Rome, Italy

Stephen Goldrick

Machine learning and advanced data analytics to better exploit process analytical technology for chromatography operation

Recovery of Biological Products XIX Conference

10-15 July 2022, Rome, Italy

Siamak Naderi

Rolling Horizon Scheduling of Biopharmaceutical Therapies via a Two-Step Lookahead Heuristic

European Conference on Operational Research (EURO 2022)

3-6 July 2022, Espoo, Finland

Andrea Bernardi

A bi-level decomposition approach for CAR-T cell therapies supply chain optimisation

14th International Symposium on Process Systems Engineering PSE2021

19-23 June 2022, Kyoto, Japan

Niki Triantafyllou

Fresh vs frozen: assessing the impact of cryopreservation in personalised medicine

32nd European Symposium on Computer Aided Process Engineering (ESCAPE32)

12-15 June 2022, Toulouse, France

Igor Andreyev

Perspective optical and microfluidic modalities for emerging non-invasive analytical platforms

Cell and Gene Therapy Innovations conference

24-25 May 2022, Berlin, Germany

Suzanne Farid

Cost of goods and commercialization analysis for ATMPs

Advanced Therapies Congress

24-25 May 2022, London, UK

Beatrice Melinek

Rapid iterative design of tandem-core virus-like particles using Escherichia Coli-based cell-free protein synthesis

ECl, microbial fermentation II

3-7 April, 2022, Albufeira, Portugal

2021

Igor Andreyev

Poster: Label free recognition of non-activated and activated T cells by Quantitative Phase Imaging on a chip

EUROPT(R)ODE XV

11 November-1 December 2021, Warsaw, Poland (Online)

Andrea Bernardi

Multi-Objective Supply Chain Optimization in Personalized Healthcare

AIChE Annual Meeting

5-11/15-19 November 2021 Boston MA and Online

Paul Dalby

Co-organiser and Session Chair: Novel Protein Formats.

BioProNet

8-9 November 2021, Online.

Stephen Goldrick

PAT and Adaptive Manufacturing- Roundtable Discussion

5th October 2021

Stephen Goldrick

High-Throughput Raman Spectroscopy Combined with Innovative Data Analysis Workflow to Enhance Biopharmaceutical Process Development

BioTalk US - Biological Manufacturing Excellence

12th October 2021, Online

Annual Report 2021

Paul Dalby

Panel member: Revolution not evolution of Biologics production.

PharmaTechIntegrates 2021

23 Sept 2021, Online.

Stephen Goldrick

Raman spectroscopy for biomanufacturing operations: Practical challenges, modelling issues and opportunities

CPACT's Webinar

2nd September 2021, Online

Nourredine Himoudi

Toxicity Risks of Adeno-associated Virus (AAV) Vectors for Gene Therapy (GT)

FDA Cellular, Tissue, and Gene Therapies Advisory Committee Meeting

2-3 September 2021, Online

Suzanne Farid

Oral Session Chair: Implementation: It's Happening

ACS Fall 2021 Meeting & Expo

22-26 August 2021, Atlanta, GA & Virtual

Andrea Bernardi

Multi-objective supply chain optimization in personalised healthcare

European Conference on Operational Research (EURO 2021)

11-14 July 2021, Athens, Greece and Online

Suzanne Farid

Decisional tools for continuous bioprocess economics and predictive data mining for mAbs.

Process development: Go smarter, go faster! GSK/Cytiva Conference

30 June-1 July 2021, Online

Andrea Bernardi

Assessment of intermediate storage and distribution nodes in personalised medicine

The 31st European Symposium on Computer-Aided Process Engineering (ESCAPE-31)

6-9 June 2021, Istanbul, Turkey and Online

Maryam Shariatzadeh

Multi-level modelling approach for cost effective t-cell manufacture

International Society for Cell and Gene Therapy (ISCT 2021)

26-28 May 2021, New Orleans USA (virtual)

Suzanne Farid

Workshop Session Chair: Plant Modelling

4th Mini Modelling Workshop 2021 (Recovery of Biological Products Satellite)

25 May 2021, Online

Suzanne Farid

Biopharma decisional tools for cost-effective process design, facility fit and capacity planning decisions:
Industrial case studies

4th Mini Modelling Workshop 2021 (Recovery of Biological Products Satellite)

25 May 2021, Online

Suzanne Farid

Economics of viral vector manufacture for cell and gene therapy commercialisation

Advanced Therapies Congress & Expo

19-21 May, 2021, Online

Qasim Rafiq

Establishing a process intensification and adaptive manufacturing strategy for CAR-T production

Advanced Therapies Congress & Expo

19-21 May, 2021, Online

Beatrice Melinek

A rational approach to designing cell-free synthesis based biomolecule platform screening processes

PEGS Boston Conference and Expo

11-13 May 2021, Online

Paul Dalby

Combining Biophysics and Modelling Approaches to Better Understand and Predict Protein Stability in Formulations.

CHI Bioprocessing Summit

16-17 March 2021, Online.

Suzanne Farid

Decisional tools to assess next-generation biomanufacturing strategies for antibodies and ATMPs

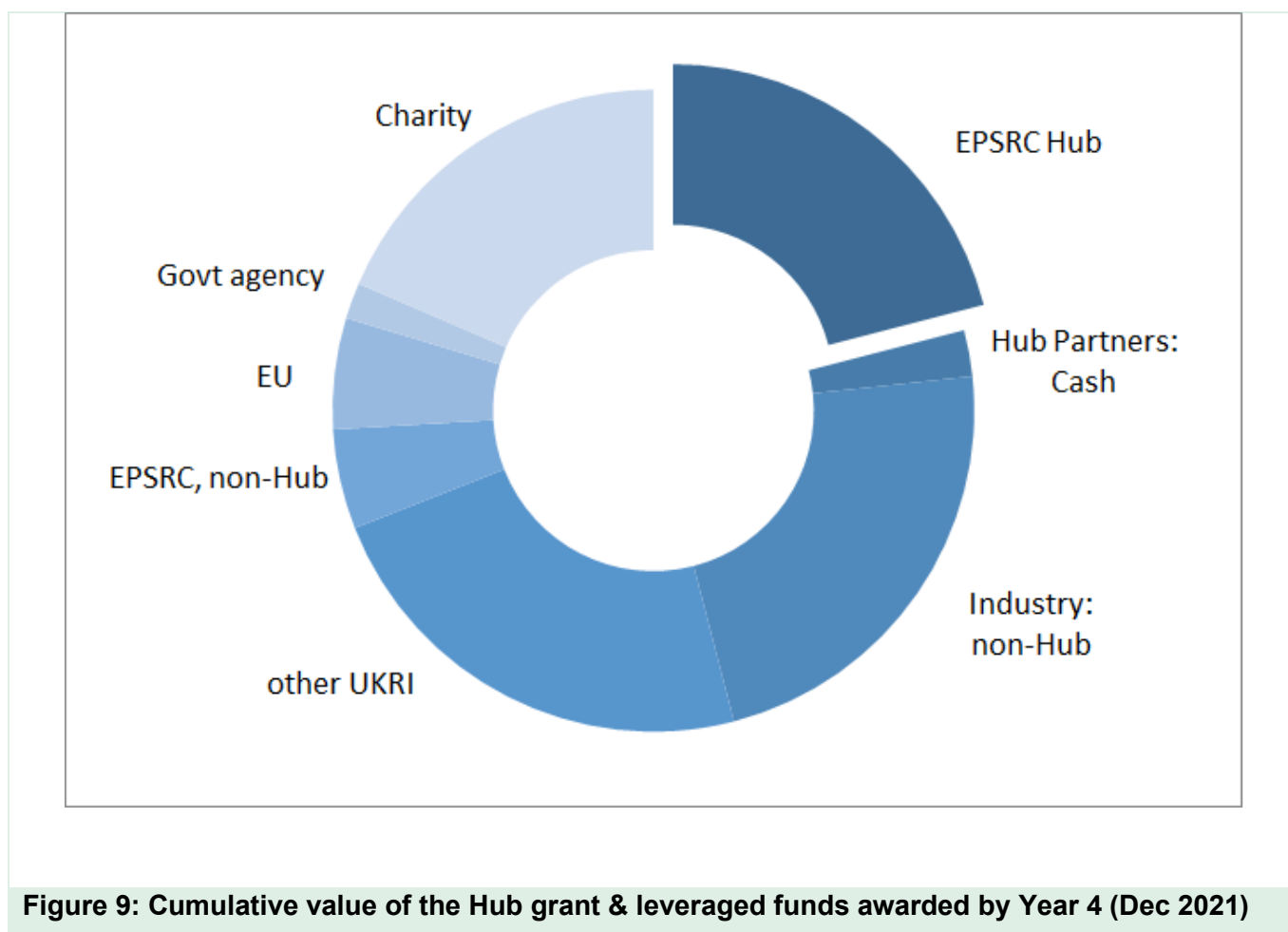
Lonza Seminar Series

3 March 2021, Online

FINANCES



Leveraged Funding



Growth of the grant portfolio associated with the Hub is an important metric of success. We have pursued a number of different avenues, including companies, government agencies and UKRI. The Hub has secured approximately £27M from external sources, which complements the £7.4M EPSRC core funding for the first five years of the Hub, to December 2021. In addition to this, Users have pledged in-kind contributions to the value of £8M to date.

