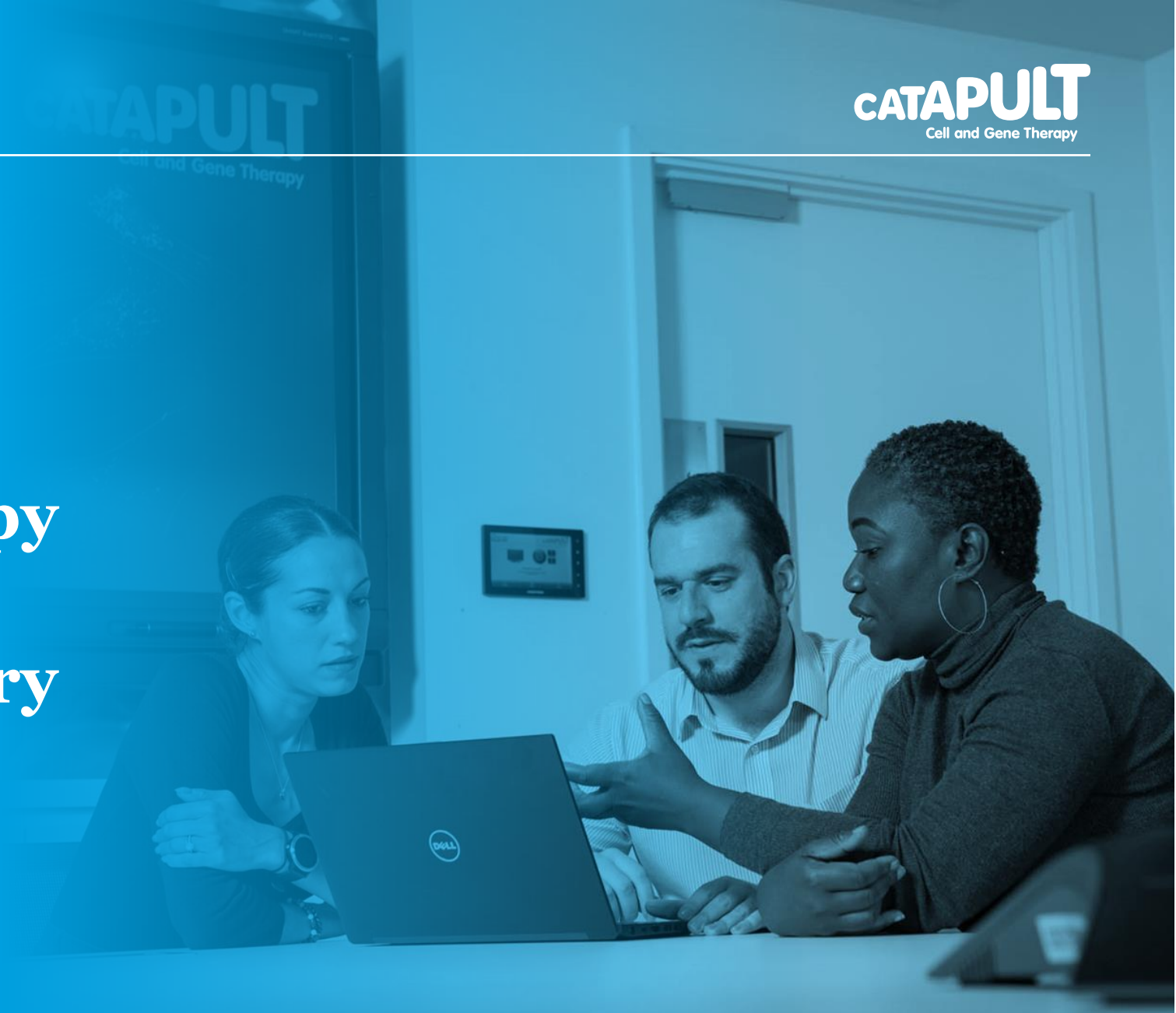
Cell and Gene Therapy Catapult:

UK and EU Regulatory Affairs



Clinical Trials Support

- Cell and gene therapy products are complex and provide unique scientific and regulatory challenges when compared to more conventional medicines
- The regulatory affairs team are cell and gene therapy specialists, with a strong core of expertise in the support of clinical studies
- The regulatory affairs team works with the non-clinical and clinical teams alongside a network of clinical experts to provide access to expertise across a number of different technologies and therapeutic areas to:
  - Provide non-clinical advice and gap analysis
  - Prepare Investigational Medicinal Product Dossiers (IMPDs) and perform conversions from IND to IMPD
  - Prepare and submit CTA, ethics committee and GMO documentation with extensive experience in the UK and EU
  - Handle all interactions with all regulatory and environmental agencies during the assessment phase

Regulatory Procedures

We have guided and overseen a variety of European regulatory procedures, and can provide our experience and expertise to assist in procedures and documentation of the following:

- Orphan Medicinal Product Designations
- Orphan similarity assessment
- ATMP Classification
- Paediatric Investigation Plans
- Applications for SME Status
- PRIME applications, and applications for Accelerated Assessment
- Environmental Risk Assessments
- Marketing Authorisation Applications (Modules 1-4)

Development Support

- We have facilitated many companies with national agency and EMA scientific and regulatory advice procedures throughout development
- We can:
  - Author or review briefing documentation
  - Author and review presentations made to agencies
  - Provide rehearsal meetings
  - Provide advice based on our extensive experience on how to get the most out of these meetings

Our Team

Our reach and experience

- Head of Regulatory Affairs is a co-chair of the European Alliance for Regenerative Medicine (ARM) regulatory affairs committee and sits on the BIA Regulatory Affairs advisory committee, with 14 years experience in regulatory affairs and product development related to cell and gene therapies
- Our team has three Senior Regulatory Managers with 30 years of collective experience in regulatory affairs and early to late stage product development
- We have navigated our way around a variety of regulatory submissions and procedures throughout Europe (national and centralised) and can help with approaching and working with regulators
- Our team can draw on their previous experiences within a variety of organisations including large pharma, biotech, regulatory agencies, service providers and academia.
- Our team includes specialists in CMC regulatory affairs with experience of preparing module 3 dossiers for CTA and MAA applications.
- Our team has native language speakers from several European countries which can help facilitate interactions with local authorities

CATAPULT
Cell and Gene Therapy

12th Floor Tower Wing
Guy's Hospital

Great Maze Pond
London SE1 9RT

info@ct.catapult.org.uk
ct.catapult.org.uk
Twitter: @CGTCatapult

Cell and Gene Therapy Catapult is committed to ensuring high standards of research integrity and research best practice in the activities we carry out. We subscribe to the principles described in the UK concordat to support research integrity.

UKRI Innovate UK