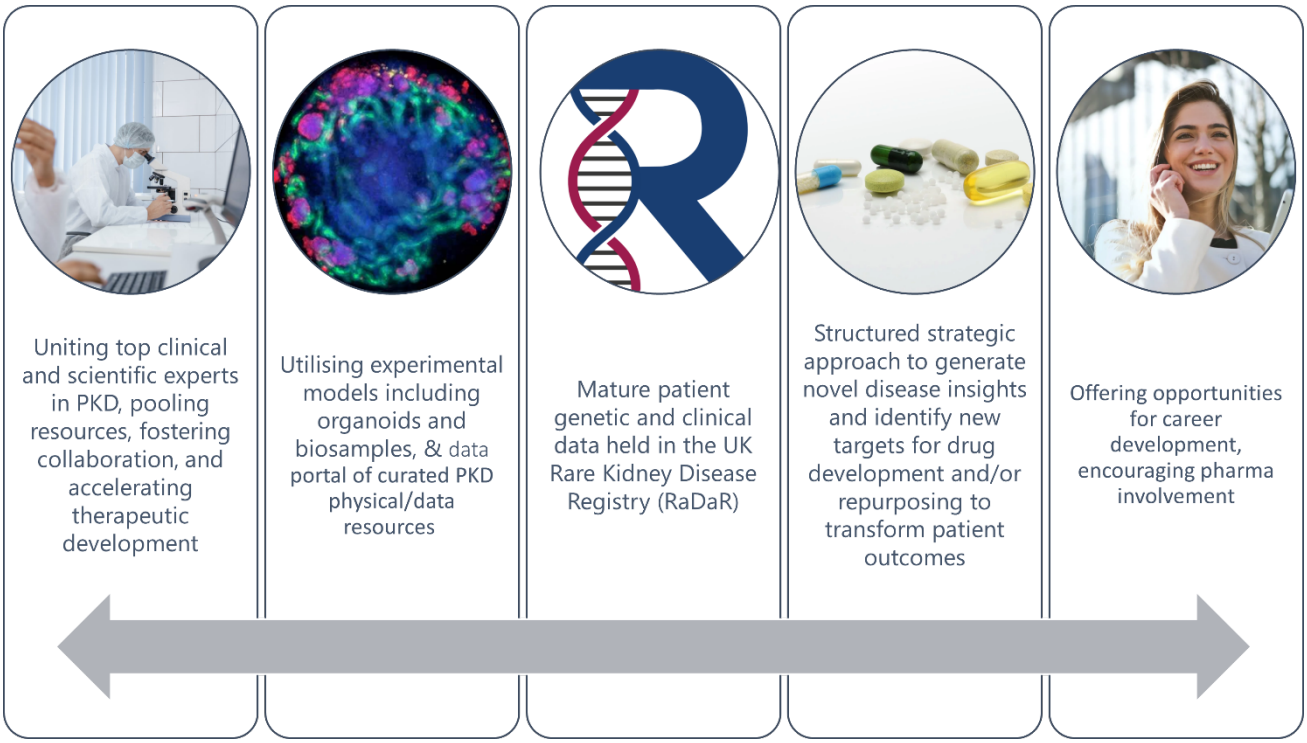
PKD Research Consortium Consultancy Brief

PKD Charity (PKDC) and Kidney Research UK (KRUK) have formed an alliance to boost research and development in polycystic kidney disease (PKD). PKD, the world's most common inherited kidney disease, has significant unmet needs and limited therapeutic options. We will form a PKD Research Consortium, bringing together clinical and scientific experts in PKD and related rare conditions, to pool resources, drive collaboration and accelerate therapeutic development.



The consortium will be a robust collaborative platform bringing together experimental models including organoids and biosamples, and pursue the detailed interrogation of mature patient genetic and clinical data held in the UK Rare Kidney Disease Registry (RaDaR). This structured strategic approach will generate novel disease insights and identify new targets for drug development and/or repurposing to transform patient outcomes.

We require consultancy services to undertake a scoping study to help us establish the consortium.

The PKD Consortium overview (see infographic below)

- An infographic has been enclosed of our initial 'vision/concept' for illustration for information purposes.
- A network of adult and paediatric centres, led by known PKD experts (kidney/other organs) with international links.
- A data portal of curated PKD physical/data resources including: the UK Rare Renal Registry (RaDaR), the PKD Biobank of tissue/cell lines (based at UCL/Royal Free), the National Unified Renal Translational Research Enterprise (NURTuRE), mouse models, imaging data, genomics (Genomics England and NHS), assays, biomarkers.
- Strategic oversight will be provided by the PKDC/KRUK Research Programme Board.
- The consortium will collaborate closely with the UK PKD Clinical Study/Rare Disease Groups (academic/hospital/patients' networks).

Proposed scoping study

Summary of requirements:

Governance

- The consortium will be overseen by the PKDC/KRUK Research Programme Board (RPB), established in 2020 to ensure fulfilment of both charities' vision to 'understand the key drivers of progressive PKD, identify new therapies and improve patient outcomes within 10 years'.
- We require guidance on:
    - A recommended overall approach/critique on the enclosed infographic
    - Overall governance oversight by the RPB
    - Type of project agreement/collaboration/commitment between all parties needed to assign rights and responsibilities between partners, protect and capture intellectual property, and address liability for external and internal claims.
    - We need procedures and processes for decision-making and voting, as well as an understanding of each institution's way of operating, contractual and institutional arrangements, key personnel, and potential barriers. Our goal is to standardize agreements, SOPs, and other key documents.
    - Data sharing, material transfer agreements, and access to consortium-generated data, as well as terms for future funding agreements.

Information collection from centres

- Consultation will be required with key stakeholders, including personnel within the intended academic centres (expected to be 8-10 organisations such as UCL/Royal Free, Sheffield, Newcastle).
- We need to collect data from various sources, including databases or collections of data, biosamples (with GDPR access status), computer models/algorithms, data analysis techniques, interoperability, datasets, research tools and methods.
- Diagnostic tools, including imaging and non-imaging tools (by research/clinical development stage), software or webtools, and apps, are also areas of focus.

Barriers/opportunities for clinical trials

- We are interested in opportunities for the consortium to bring together clinical trial centres, fund coordinators, and support trials in the future in collaboration with RaDaR. We need guidance on the requirements for such an initiative and how it could be accomplished (see example of the Cystic Fibrosis Trust Trials Platform).

References/links

Kidney Research UK

Polycystic Kidney Disease Charity

RaDaR

NURTuRE https://www.kidneyresearchuk.org/2019/04/01/nurture-biobank/

PKD Biobank https://pkdcharity.org.uk/research/pkd-uk-research/pkd-bioresource-bank

Infographic