EXPERTISE AND CAPABILITIES

The TRC in Inflammatory Respiratory Disease provides cutting-edge expertise in the development of exploratory protocols, biomarkers discovery, and an understanding of pathophysiology and disease mechanisms in a range of inflammatory lung conditions, including:

- asthma
- chronic obstructive pulmonary disease (COPD)
- interstitial lung diseases, in particular idiopathic pulmonary fibrosis (IPF) and sarcoidosis
- acute lung injury including acute respiratory distress syndrome (ARDS)
- cystic fibrosis and other rare respiratory diseases.

The TRC regularly reviews areas of unmet clinical need to determine emerging topics of focus for the group.

The TRC centres have an outstanding track record in undertaking clinical research and efficient delivery of phase I first-into-disease studies and phase II studies.

The TRC can provide industry partners with:

- expertise in the complete range of translational research, including:
  - access to lung tissues from patients for ex vivo validation work
  - validation and optimisation of biomarkers for incorporation in innovative proof-of-concept studies
  - knowledge management platforms and bioinformatics

- access to state-of-the-art clinical and laboratory facilities to support complex procedures and investigations including:
  - molecular and functional imaging of the lung including techniques such as FDG-PET
  - bronchoscopy, lung biopsies and bronchoalveolar lavage
  - capabilities for frequent repeat blood and urine sampling, enabling pharmacokinetic and pharmacodynamic early phase studies
  - biobanks to support the collection and management of large numbers of blood and tissue samples in multi-centre clinical studies.

The TRC also has strategic links with other UK and European academic networks, such as the ERS Clinical Research Collaborations, and platforms established in relevant therapeutic indications, including the European asthma initiative Unbiased Biomarkers in Prediction of Respiratory Disease Outcomes (U-BIOPRED) and the UK-based COPD biomarker consortium (COPDMAP).
WHAT ARE THE TRANSLATIONAL RESEARCH COLLABORATIONS?

The NIHR Translational Research Collaborations (TRCs) are ready-formed partnerships of leading universities and NHS hospitals set up to work with the life sciences industry. They carry out translational research and tackle experimental medicine challenges in selected therapeutic areas.

The TRC in Inflammatory Respiratory Disease provides access to world-leading academic clinicians and scientists who have significant expertise in a wide range of inflammatory lung conditions. These experts, who are based within cutting-edge research centres across the UK, have access to well-characterised patient cohorts and are available to work collaboratively with industry.

“By working with the TRC in inflammatory respiratory disease, we gained invaluable advice on design and conduct of a study in bronchial asthma. The TRC enabled us to access network of leading UK research sites and we completed our study across 6 UK sites ahead of schedule.”

AstraZeneca Global study Team

WHO CAN WORK WITH THE TRC?

The TRC is available to work collaboratively with all sectors of the life sciences industry, including Contract Research Organisations, and charities to further research in inflammatory respiratory disease and to help develop new diagnostics and treatments. They can undertake commercial and non-commercial studies.
WORKING WITH THE TRANSLATIONAL RESEARCH COLLABORATION

The NIHR Office for Clinical Research Infrastructure (NOCRI) provides a dedicated team that acts as an effective, single point of contact for companies who wish to engage with the TRC. Liaising closely with the TRC centres, industry and/or charity partners and Contract Research Organisations, the NOCRI team supports all steps from first contact through to the completion of a study. A standard two-way non-disclosure agreement (NDA) is used to allow detailed discussion of new project opportunities. The NDA template is endorsed and agreed by all TRC centres, enabling the agreement to be put in place within 10 working days.

Once an NDA is in place, study set-up and completion are supported by NOCRI through three key stages:

**STAGE 1 - EARLY ENGAGEMENT**
TRC investigators work with a company to generate a protocol and carry out a robust feasibility assessment.
- Protocol development
- Feasibility

**STAGE 2 - STUDY SET-UP**
NOCRI and the Operational Leads at TRC centres provide support throughout the set up process including costing, contracting and local R&D reviews. NOCRI support includes acting as the point of escalation should issues arise.
- Costing
- Contracting
- Study submission and approvals

**STAGE 3 - STUDY DELIVERY**
Delivery of studies to time and target is a key commitment. NOCRI liaises with the Sponsor/CRO to monitor study performance and escalate any issues. If required, the TRC can work with other research centres across the country to bring in additional expertise and/or patients.
- First patient / first visit
- Recruitment to time and target
“The TRC’s unique model of collaboration between UK respiratory centres of excellence and industry is enhancing our understanding of complex disease mechanisms and will accelerate the development of new treatments and diagnostics to tackle areas of unmet healthcare needs.”

TIM HARRISON, Chair of the TRC in Inflammatory Respiratory Disease
BENEFITS OF WORKING WITH THE TRC

The TRC provides easy access to a network of academic centres and experts, with a broad range of expertise and capabilities, embedded in UK universities and NHS hospitals who are available to work collaboratively on early phase clinical studies.

The TRC investigators can provide the life science industry with expert advice on the design of early phase studies to inform clinical development programs and access to well-characterised cohorts of patients through close interaction with academic initiatives and strong links with patient associations and national disease registries.

The TRC centres operate to common business processes, including standard operating procedures across a number of sites to facilitate multi-centre studies. This makes it quicker and easier for industry to work with the expert investigators within the NHS.

The TRC provides operational support, including a standard pre-approved non-disclosure agreement, contractual templates and a close working relationship with the NIHR Clinical Research Network to access its study support services as relevant.

“Working with the TRC in Inflammatory Respiratory Disease on our study helped with our site engagement and to raise the profile of the study at these sites. Our NOCRI contact was always available to discuss any challenges and to help ensure the smooth delivery of the study.”

ANDREW BAKER, Project Manager, Boehringer Ingelheim

When to contact the TRC

If you have an asset that you would like to develop and you are looking to access the expertise of the TRC to shape your protocol and provide expert advice on study design, then contact the NIHR Office for Clinical Research Infrastructure.

NIHR Office for Clinical Research Infrastructure
nocri@nihr.ac.uk
+44 (0)20 3794 7380
Minerva House, 5 Montague Close, London SE1 9BB
www.nihr.ac.uk/translational_research_collaborations

@NIHR_NOCRI
@nihr-office-for-clinical-research-infrastructure