



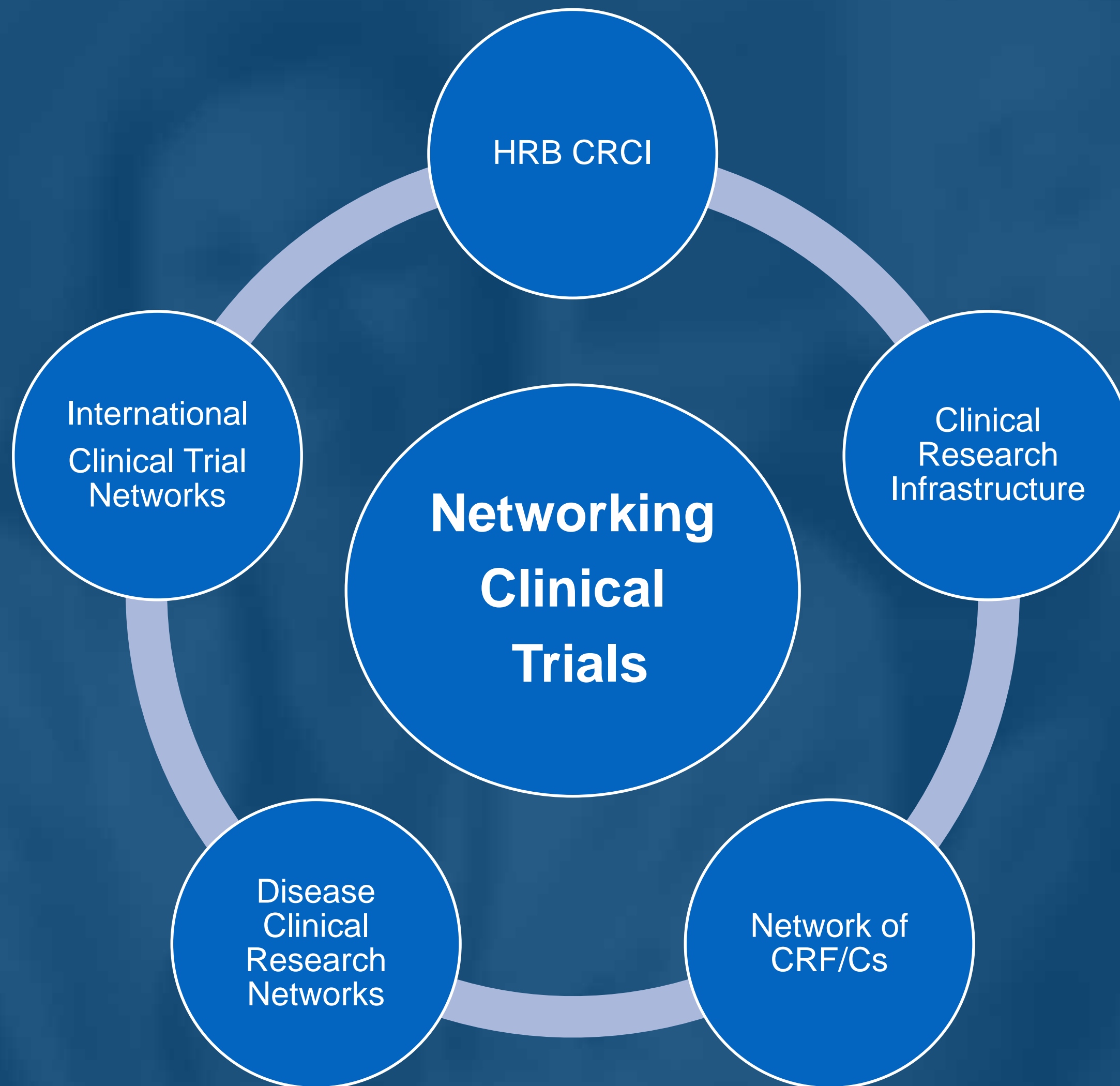
Health Research Board

CROI

Clinical Research Coordination Ireland

Networking Clinical Trials

Anna Shevlin, Clinical Trial Liaison Officer



Network Based Research:

Clinical Trials Networks underpin the conduct of large scale multicentre clinical trials by providing:

- Central point of contact
- Central coordination of clinical trials
- Access to large numbers of subjects nationally and internationally
- Single standardised network response to feasibility assessments
- Opportunity to compete in large scale grants/tenders as a single entity
- Facilitate a uniform response to contractual and ethical obligations
- Cost effective and efficient streamlined structures

HRB CRCI

HRB Clinical Research Coordination Ireland

HRB Clinical Research Coordination Ireland

- A national integrated clinical research network of the Clinical Research Facilities/Centres (CRF/C) in Ireland
- Providing overarching support and coordination of multicentre clinical research activities
- Co-Funded
 - Health Research Board,
 - Enterprise Ireland
 - 5 Universities – Molecular Medicine Ireland
- Established 1 May 2015



HRB Clinical Research Coordination Ireland



HRB CRCI also collaborates with:

- HRI CRSU Limerick
- NICRF Belfast City Hospital
- NCRC Our Lady's Children's Hospital, Crumlin
- Individual Investigators
- Clinical Research Networks



**CRF/C
Director**



**CRF/C
Director**



CRCI Chair
(CRF/C Director)



**CRF/C
Director**



**CRF/C
Director**



**MMI
CE**



**HRB CRCI
COO**

HRB CRCI
Senior
Management
Team

COO

CILO

CTLO

QM

**Corp. Support
Services**



HRB CRCI
Central Office

Lead

SS

RN



Lead

SS

RN



Lead

SS

RN



Lead

SS

RN



Lead

SS

RN



**HRB CRCI
CRF/C
Based Staff**

Vision for HRB CRCI

“That Ireland is internationally recognised for conducting innovative high quality clinical research for the benefit of people’s health and the economy.”

Aims of HRB CRCI

- To provide the skills, expertise and infrastructure to design, conduct and analyse **multi-centre clinical trials** involving human participants in Ireland
- To support both **academic and industry** initiated clinical trials involving pharmaceuticals, neutraceuticals or clinical care pathways as well as clinical investigation of medical devices
- To enhance Ireland's capacity for conducting **innovative high quality clinical research** for the **benefit of people's health and the economy**
- To **advance the care of patients** by enabling a **connected and coordinated Clinical Trial Network**

HRB CRCI Services and Activities

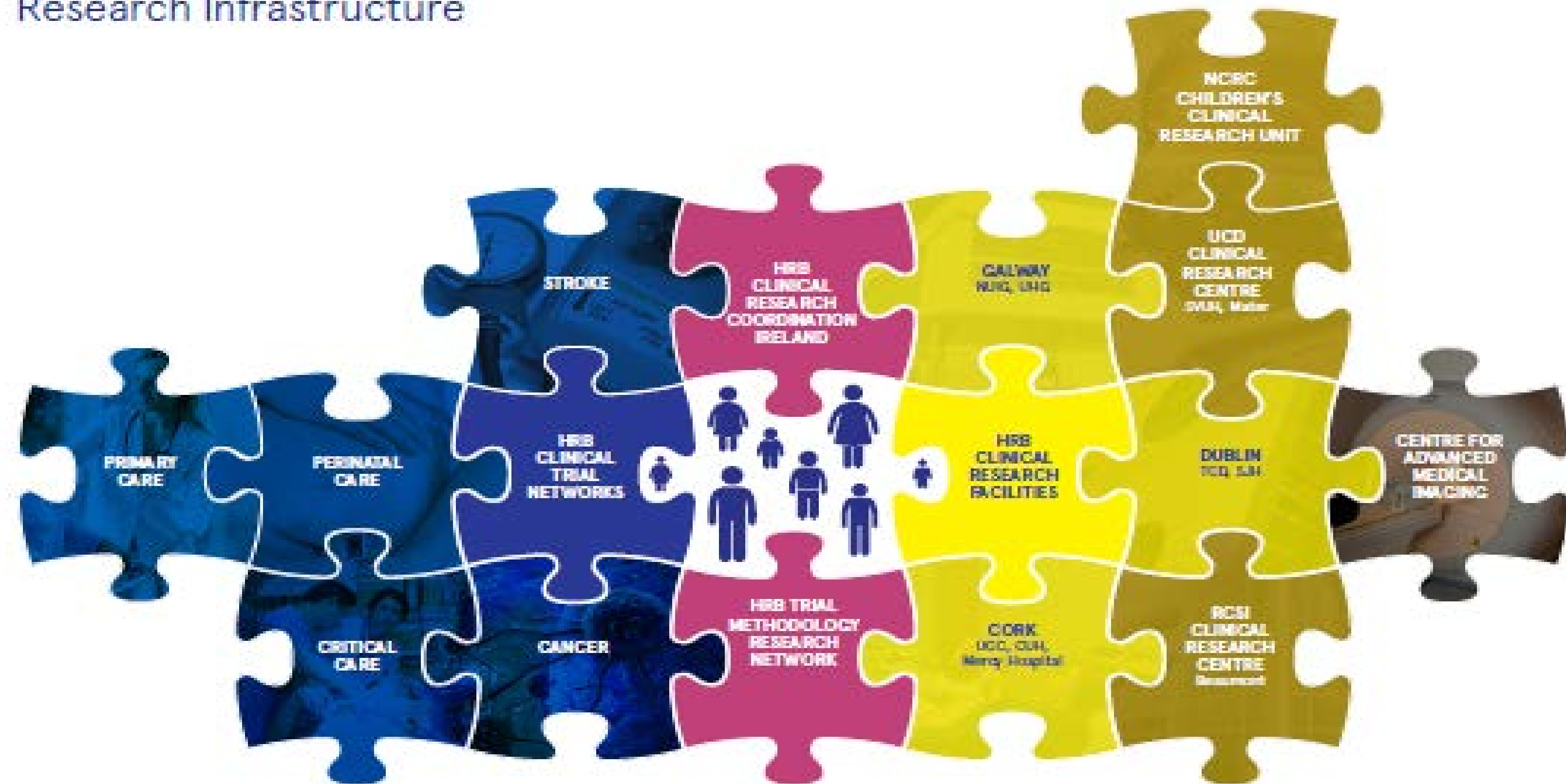
Based on UK Model of support (e.g. NHS Research Scotland, NIHR CRN) and in response to Irish clinical research gap analysis

1. **Signposting** - Central point of contact/efficient, knowledgeable & accurate
2. **Study feasibility** - streamlined national process
3. **Study start-up** – Improve study start-up timelines
4. **Recruitment tracking** - collation of metrics
5. **Promotion** – ambassadors for Irish clinical research and innovation
6. **Advisory/Consultancy** – regulatory pathways
7. **Regulatory and Ethics** – application process
8. **Audit and Monitoring** - oversight of study conduct
9. **Quality working group** - harmonisation
10. **On-line services** – www.hrb-crci.ie

Clinical Research Infrastructure

Patient-Focused Research for Better Health & Care

HRB Creating A Strong Clinical
Research Infrastructure



Strong infrastructure, world class clinical and academic expertise and embedding clinical research within our health system is essential for a vibrant research environment in Ireland.

A blue silhouette map of Ireland is centered on the slide. Five white location pins are placed on the map: one in the north, one in the center, one in the south, and two in the east. The text 'Network of CRF/Cs' is overlaid on the map.

Network of CRF/Cs



Health Research Board
CRCI
Clinical Research Coordination Ireland

Network of CRF/Cs



Collaborating CRF/Cs:

- HRI CRSU Limerick
- NICRF Belfast City Hospital
- NCRC Our Lady's Children's Hospital, Crumlin

Clinical Research Centres/Facilities:

The CRF/Cs are active collaborations between the hospitals and the universities.

The Clinical Research Facilities and Centre's (CRF/Cs) provide:

- the infrastructure
- physical space and facilities
- experienced research and specialist support staff
- and the necessary quality and oversight programs that are critical for the successful conduct of safe and effective world-class patient-focused research

Previously sites lead and participated in joint projects on a project specific basis.
HRB CRCI provide an overarching support structure to coordinate multicentre clinical trial activities

Centre Metrics (Nov 2015) Apr 2016

No. of CRF/C's



No. of combined years performing CT in the CRF/C



No. of clinical trial study sites open in (2014) 2015 across the 6 centres



No. of Staff directly employed by the 6 centres



(119) 134

No. of hospitals participating in research studies through the CRF/C's



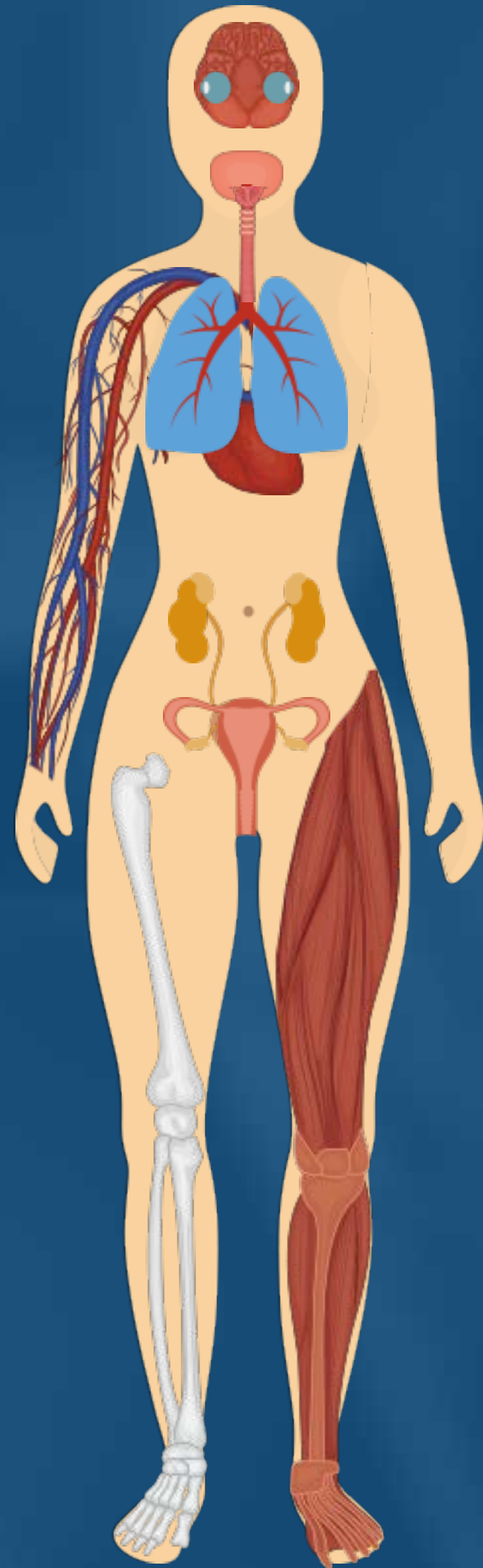
(13) 14

No. of Clinical Investigators affiliated with the 6 CRF/C



(216) 253

Clinical trials ongoing in 26 Therapeutic Areas



1. Renal
2. Rheumatology/Musculoskeletal
3. Respiratory
4. Cardiology
5. Vascular disease
6. Neurology
7. Dermatology
8. Gynaecology
9. Endocrine
10. Neonatal
11. Urology
12. Stroke
13. Psychiatry

14. Ophthalmology
15. Oral and Gastroenterology
16. Hepatology
17. Haematology
18. Oncology
19. Critical Care
20. Infectious Disease
21. Metabolism
22. Geriatric
23. Anaesthesia
24. Physiotherapy
25. Occupational therapy
26. ENT

HRB CRCI Quality Working Group (QWG)

The QWG consists of quality and training representatives from each of the partner CRF/Cs and is chaired by the HRB CRCI Quality and Regulatory Affairs Manager, Ms. Sinead Curran.

The QWG's mission is to facilitate cooperation and sharing within the CRCI partnerships with respect to quality, compliance and training matters, such that harmonisation is promoted, duplication is avoided and available resource is maximised

One Important Key Objectives:

Agree minimum standards for quality systems, thereby laying the foundation for mutual recognition amongst partners.

A map of Ireland is shown in light gray against a dark blue background. Overlaid on the map is a network diagram consisting of numerous circular nodes of varying sizes, colored in shades of green, blue, and cyan. These nodes are interconnected by a web of thin, light-colored lines, representing a network structure across the geographical area of Ireland.

Disease/Clinical interest Clinical Research Networks

Clinical Research Networks (CRN)

A CRN is a group of clinicians who come together around a clinical interest and agree on research activities best conducted as a large group rather than in isolation.

HRB CRCI work with and support a number of CRN.

A number of CRNs have been established through state funding while others are funded mainly through charitable funds; ICORG in oncology being the most established CRN.

The HRB recently funded the establishment of four new Clinical Trial Networks

- HRB Stroke Clinical Trial Network Ireland
- HRB Critical Care Clinical Trials Network Ireland
- HRB Mother & Baby Clinical Trials Network Ireland
- HRB Irish Primary Care Clinical Trial Network

Networks work closely with a wide range of stakeholders including patients, carers, researchers, charities, hospitals, CRF/Cs, academic institutions, healthcare professionals and commercial organisations.

23 Clinical Research Networks

HRB CRCI works with and supports a number of clinical research networks. Clinical research networks are groups of clinicians and scientists from across Ireland who have come together around a particular disease, or clinical interest. Investigators agree on research activities that are best conducted as a large group nationally rather than in isolation.

A number of clinical research networks have been established and are listed below by research area. Some receive state funding while others are funded mainly through charitable funds. The Health Research Board recently funded the establishment of four new Clinical Trial Networks in stroke, critical care, perinatal care and primary care.

The clinical research network page is live and updated on an ongoing basis. If you are a lead of a clinical research network and would like it included on the HRB CRCI website please contact info@hrb-crci.ie

Overview of Research
Infrastructure

Clinical Research Facilities /
Centres

HRB CRF Cork

HRB CRF Galway

Wellcome Trust HRB CRF SJH

Many CRNs support the delivery of a range of high quality studies across a spectrum of disease and clinical need.

International Clinical Trial Networks



Comparison of clinical trial activity between Ireland and other countries of similar size

Country Population	Clinical Trials Open 2011	Clinical Trials Open 2014*
Denmark (5 million)	928	1012
Finland (5 million)	336	367
Norway (5 million)	521	543
Sweden (9 million)	650	806
Ireland (5 million)	185	224

SNAPSHOT: Including only open studies, excluding studies with unknown status
Data Source: Clinicaltrials.Gov

Review of Services elsewhere

The primary common themes of other jurisdictions are

- The integration of research as a fundamental component of the health service provision and
- a centralised coordinating service.

Example:

- NIHR CRN: National Institute for Health Research CRN
- NRS: NHS Research Scotland
- D-CRIN: Danish Clinical Research Infrastructures Network
- F-CRIN: French Clinical Research Infrastructure Network

[About the CRN](#)[How we can help](#)[Discover the Network](#)[Contact us](#)

The Clinical Research Network: delivering research to make patients, and the NHS, better

We provide the infrastructure that allows high-quality clinical research to take place in the NHS, so that patients can benefit from new and better treatments. We help researchers to set up clinical studies quickly and effectively; support the life-sciences industry to deliver their research programmes; provide health professionals with research training; and work with patients to ensure their needs are at the very centre of all research activity.

Our Study Support Service helps the clinical research community deliver their studies in the NHS. Find out how we're helping to bring research to patients...



Early contact
and engagement



YouTube

NHS Research Scotland

**Involving patients and the public in
health research**

Get involved

Industry

Co-ordinated, efficient and reliable

[Learn more →](#)

Researchers

Funding, resources, training and academic...

[Learn more →](#)

Public

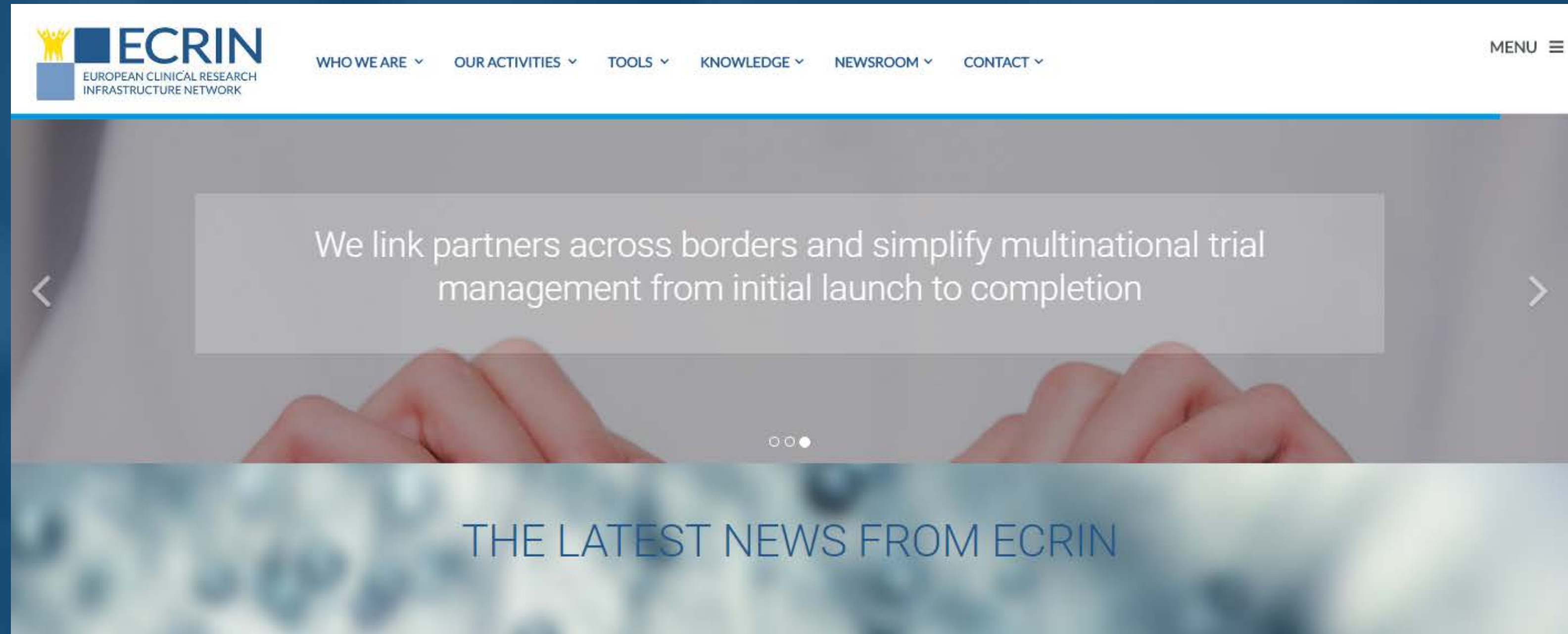
Help us find new and better treatments

[Learn more →](#)

Through NHS Research Scotland a strong infrastructure has been developed that is appealing to industry and delivers Scotland as a single clinical research site with accessible and streamlined approval and contractual processes.



ECRIN - European Clinical Research Infrastructure Network



- ECRIN supports the conduct of multinational clinical trials in Europe.
- Connect networks.
- ECRIN focuses on the conduct of independent trials.
- Horizon 2020.

International Clinical Trial Networks

There are multiple International Disease Networks which Ireland link in to.. e.g.

- Eastern Cooperative Oncology Group (ECOG)
- Breast International Group (BIG) - breast cancer research group
- European Network of Paediatric Research at the EMA (Enpr-EMA)
- CFMATTERS Consortium
- COMBACTE - Combatting Bacterial Resistance in Europe

The screenshot shows the homepage of the ECOG-ACRIN cancer research group. The header features the logo with the text "ECOG-ACRIN cancer research group" and the tagline "Reshaping the future of patient care". Navigation links include Home, About Us, Scientific Programs, Research Support, Research Cores, Resources, Patients, News and Info, and Contact Us. A "Member Login" button and a search bar are also present. The main content area is titled "ECOG Performance Status" and includes two statistics: "80 Active Clinical Trials" and "Participating Institutions". Below this are three images: a microscopic view of cells, a scientist in a lab coat using a pipette, and a doctor consulting with a patient. A text block explains the purpose of clinical trials and the ECOG Scale of performance status. A "Resources" sidebar on the right lists "Group Meetings".

ECOG-ACRIN
cancer research group
Reshaping the future of patient care

Member Login

Search

Follow

Home About Us Scientific Programs Research Support Research Cores Resources Patients News and Info Contact Us

ECOG Performance Status

80 Active Clinical Trials

Participating Institutions

To conduct clinical trials for the treatment of cancer in a consistent manner across many participating hospitals, cancer centers, and clinics requires the use of standard criteria for measuring how the disease impacts a patient's daily living abilities (known to physicians and researchers as a patient's performance status). The ECOG Scale of

Resources

► Group Meetings

Achieving Our Vision

“that Ireland is internationally recognised for conducting innovative high quality clinical research”

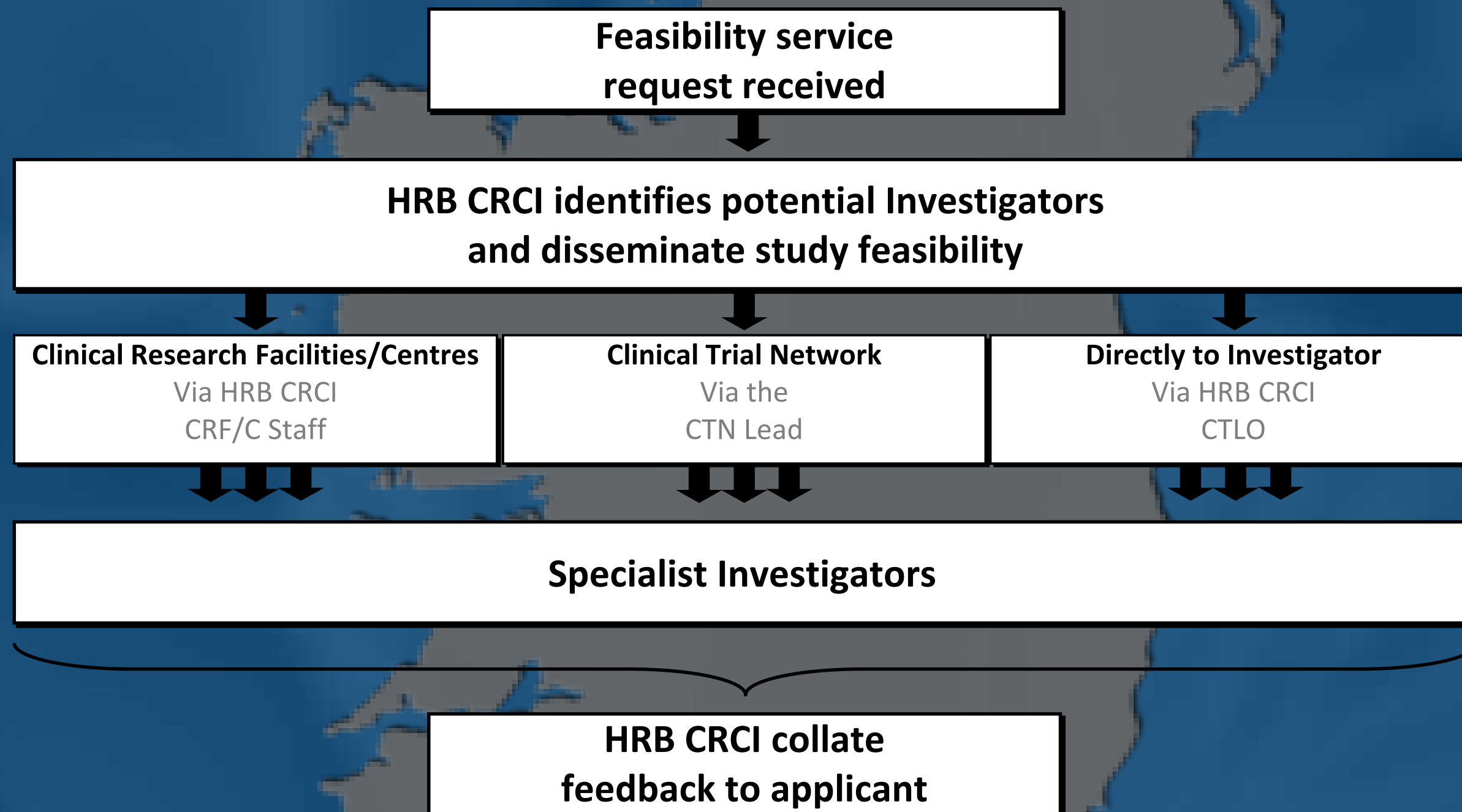
Industry Considerations:

- Choice of Clinical Trial site is dependent on:*
 1. Adherence to legislation
 2. Meeting timelines
 3. Predictability
 4. Transparency
 5. Recruitment target met
 6. Population
- Many companies operate a “preferred vendor” basis when choosing sites.
- Many companies require multiple sites to justify choosing a county.
- UK/Ireland Pharma Affiliate Office. In direct competition with the UK sites.

HRB CRCI National Study Feasibility Programme

- Study feasibility is a process through which a clinical trial sponsor (or CRO) identifies potential investigator sites and evaluates if they are suitable to conduct the clinical trial.
- Stream line national programme – Connects academic and industry sponsors with potential investigators.
- HRB CRCI act as the channel through which study feasibility assessments can be distributed and completed efficiently.
- The CRF/C network is utilised to significantly reduce the time taken to identify investigator sites and to assess study feasibility.
- Service active since Aug 2015

HRB CRCI National Study Feasibility Programme

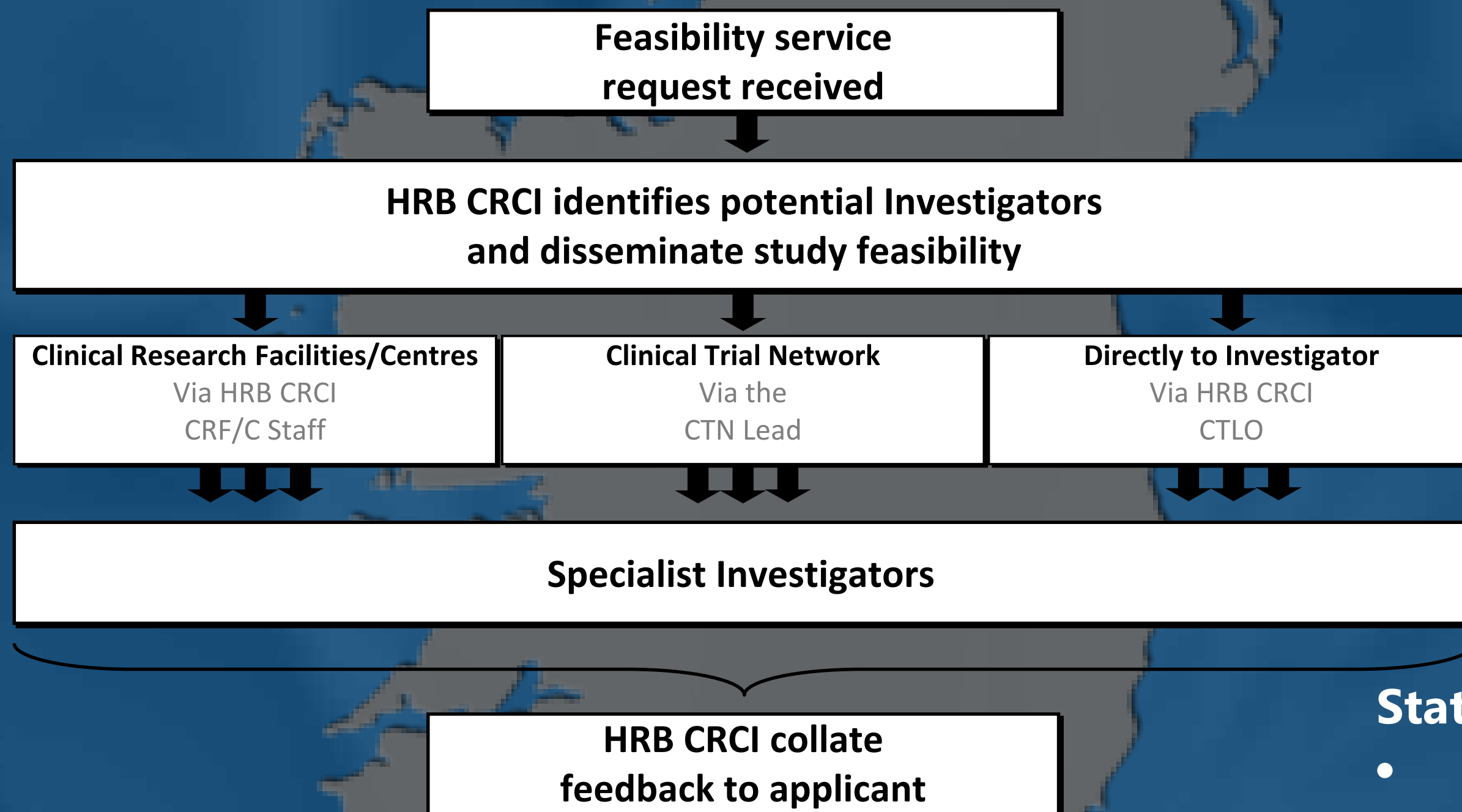


Process actively managed with an aim to feedback within 2 weeks

Disease Areas:

- Asthma
- Allergies
- Candidemia
- Cardiology
- Crohn's Disease
- Cystic Fibrosis
- Follicular lymphoma
- Gynaecology
- GI
- Haemophilia
- infectious disease
- Kidney disease
- Liver disease
- Multiple sclerosis
- Opthamology
- Paediatric cardiology
- Respiratory
- Rheumatology
- Sickle Cell Disease
- Urinary incontinence
- Vaccine

HRB CRCI National Study Feasibility Programme



Process actively managed with an aim to feedback within 2 weeks

Status update:

- 28 requests since Aug 15
- EOIs submitted for 20/28 studies
- 69 Investigator EOIs submitted
- Engaged with >109 Investigators

Thank you for your attention

www.hrb-crci.ie



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 @HRB_CRCI