Networking Clinical Trials
Anna Shevlin, Clinical Trial Liaison Officer
Networking Clinical Trials

- HRB CRCI
- International Clinical Trial Networks
- Clinical Research Infrastructure
- Disease Clinical Research Networks
- Network of CRF/Cs
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 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
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
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.
Network of CRF/Cs
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 CRC I provide an overarching support structure to coordinate multicentre clinical trial activities.
Centre Metrics (Nov 2015) Apr 2016

- No. of CRF/C’s: 6
- No. of combined years performing CT in the CRF/C: 49 yrs
- No. of hospitals participating in research studies through the CRF/C’s: (13) 14
- No. of Staff directly employed by the 6 centres: (119) 134
- No. of clinical trial study sites open in (2014) 2015 across the 6 centres: (143) 174
- No. of Clinical Investigators affiliated with the 6 CRF/C: (216) 253
- No. of hospitals participating in research studies through the CRF/C’s: (13) 14
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Clinical trials ongoing in
26 Therapeutic Areas

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<tr>
<td>2. Rheumatology/Musculoskeletal</td>
<td>15. Oral and Gastroenterology</td>
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<tr>
<td>4. Cardiology</td>
<td>17. Haematology</td>
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<tr>
<td>5. Vascular disease</td>
<td>18. Oncology</td>
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<tr>
<td>7. Dermatology</td>
<td>20. Infectious Disease</td>
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<tr>
<td>8. Gynaecology</td>
<td>21. Metabolism</td>
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<tr>
<td>9. Endocrine</td>
<td>22. Geriatric</td>
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<tr>
<td>11. Urology</td>
<td>24. Physiotherapy</td>
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<tr>
<td>13. Psychiatry</td>
<td>26. ENT</td>
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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.
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 though 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

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

**SNAPSHOT:** Including only open studies, excluding studies with unknown status

**Data Source:** Clinicaltrials.Gov

<table>
<thead>
<tr>
<th>Country Population</th>
<th>Clinical Trials Open 2011</th>
<th>Clinical Trials Open 2014*</th>
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<tbody>
<tr>
<td>Denmark (5 million)</td>
<td>928</td>
<td>1012</td>
</tr>
<tr>
<td>Finland (5 million)</td>
<td>336</td>
<td>367</td>
</tr>
<tr>
<td>Norway (5 million)</td>
<td>521</td>
<td>543</td>
</tr>
<tr>
<td>Sweden (9 million)</td>
<td>650</td>
<td>806</td>
</tr>
<tr>
<td>Ireland (5 million)</td>
<td>185</td>
<td>224</td>
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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
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.
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 supports the conduct of multinational clinical trials in Europe.
Connect networks.
ECRIN focuses on the conduct of independent trials.
Horizon 2020.
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
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 completion with the UK sites.

*Clinical Trials IPHA’s Industry perspective Oct 2015
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

HRB CRCI identifies potential Investigators and disseminate study feasibility

Feasibility service request received

HRB CRCI collate feedback to applicant

Clinical Research Facilities/Centres
- Via HRB CRCI
- CRF/C Staff

Clinical Trial Network
- Via the CTN Lead

Directly to Investigator
- Via HRB CRCI
- CTLO

Specialist Investigators

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
- Ophthalmology
- Paediatric cardiology
- Respiratory
- Rheumatology
- Sickle Cell Disease
- Urinary incontinence
- Vaccine
Status update:
- 28 requests since Aug 15
- EOIs submitted for 20/28 studies
- 69 Investigator EOIs submitted
- Engaged with >109 Investigators

Process actively managed with an aim to feedback within 2 weeks
Thank you for your attention

www.hrb-crci.ie

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