The role of CRFG in promotion of Clinical Research

Mary Byrne, Clinical Research Manager
29-Sep-2016
HRB-Clinical Research Facility Galway

March 2008
- CRFG Operations began (HRB)
- Temporary office with clinical operations in GUH

June 2015
- HRB Clinical Research Facility
  - Office space
  - 5 Consulting Rooms
  - 10 Outpatient Beds
  - 4-6 Inpatient Beds
  - Endoscopy Suite
  - Pharmacy
NUI Galway and Saolta; the Future of Clinical Research in Ireland

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative

Protective – Patients & PIs
Inclusive
Sustainable
Internationally Reputable
Streamlined
Patient focused
Specialist Workforce
Collegiate
Policy changing
High Quality
Compliant
Transparent
Competitive
Innovative
NUI Galway and Saolta; the National Research Centre Perspective

- HRB CRF Galway
- HRB CRF Cork
- WT/HRB CRF St. James’s Hospital Dublin
- RCSI CRC Beaumont Hospital Dublin
- UCD CRC Mater and St. Vincent’s Dublin
- HRI-CRSU: University Hospital Limerick
- NICRF Belfast City Hospital, Belfast

Ref. www.hrb-crci.ie
HRB-Clinical Research Facility Galway
HRB-CRFG Services

- Access to clinical specialists and networks
- Biostatistical & methodological support; study design & analysis
- Study management
- Study budget preparation and contract review
- Study protocol development
- Ethical and regulatory submissions
- Data management and IT support
- Medical writing
- Research nursing support
- Research pharmacy support
- Biospecimen collection and processing
- Controlled storage for IMPs and medical devices
- Monitoring
- Pharmacovigilance
- Education programmes
Facilities and Equipment

- Space for 28 participants/patients
- Endoscopy suite
- ECG
- Pharmacy (aseptic equipment)
- Refrigerated centrifuge
  - $-80^\circ C$, $-20^\circ$, $4^\circ$ freezers/fridges
- Access to MRI facilities
- Access to Cath lab and theatres
- Local labs
Clinical Groups

• Cancer Clinical Trials Unit (CCTU)
• Blood Cancer Network Ireland (BCNI)
• Primary Care Trials Network Ireland
• Non-Oncology Research Group
• Early Phase Trials
Research Services and Infrastructure

- Biostatistics
- Data Management
- Quality and Regulatory Affairs
- Pharmacy Clinical Trials Unit
Software Systems

- **Quality**
  - Q-pulse (SOPs, Roles)

- **Data Management**
  - EDC (MACRO-Infermed for regulated trials)
  - Paper CRF: (SPSS-Builders/iDataFax)
  - EDC (Distiller for observational)

- **Biostatistics**
  - STATA/R/SPSS (+SAS)
Clinical Research Activity

- 69 HPRA active clinical trials
- >100 studies recruiting

- Sept 2016 Stats:
  - ~6200 participants enrolled
  - ~1800 current participants

- Observational
- IMP
- ATMP
- Medical Device
Clinical Research Activity Statistics

40+ Principal Investigators

Across different phases and indications

<table>
<thead>
<tr>
<th>Phase</th>
<th>Number of trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>11</td>
</tr>
<tr>
<td>II</td>
<td>22</td>
</tr>
<tr>
<td>III</td>
<td>40</td>
</tr>
<tr>
<td>IV</td>
<td>9</td>
</tr>
</tbody>
</table>

Clinical Study Areas: Blood 21; Cancer 38; Cardiovascular 24; Generic 14; Inflammatory 2; Mental Health 7; Metabolism 25; Musculoskeletal 2; Neurological 7; Oral and Gastro 16; Renal 7; Reproduction 2; Respiratory 18; Skin 6; Stroke 3
How do you Investigators get involved with CRFG- National Networks

HRB Trials Methodology Research Network
Cancer Trials Ireland (formerly ICORG)
BCNI: Blood Cancer Network Ireland
HRB Stroke Clinical Trial Network Ireland
HRB Critical Care Clinical Trials Network Ireland
ATLANTIC DiP (Diabetes In Pregnancy)
Galway Diabetes Research Centre
Network for IBD Therapy in Ireland (INITIative)
HRB Mother & Baby Clinical Trials Network Ireland
HRB Primary Care Clinical Trial Network Ireland
Arthritis Research Coalition
Health Innovation Hub and BioInnovate

Ref. www.hrb-crci.ie
How do Investigators get involved?
NUI Galway as Sponsor of regulated clinical trials/investigations

Role of the Sponsor and as delegated
ICH-GCP E6(R1) Section 5 (with 23 subheadings)

Existing studies
- HARP-2
- CLI Trial

Upcoming studies
- EMERGE
- SATIN
- Onychomycosis Treatment Outcomes Trial
- CyBorD-Dara
Academic Research Partners

THE IRISH PRIMARY CARE RESEARCH NETWORK

LAMBE Institute for Translational Research

Academic Research Partners
Industry Research Partners
Promotion of ongoing activities

• International Clinical Trials Day
• CRFG Open Evening
• Cancer Week Ireland 2016
HRB-CRFG Training/Education

- MSc Clinical Research
  - CRA Training programme
- GCP training
- (CME/CPD Programme)
- Regular educational activities
- Workshops in Biostatistics
Thank you