Enhancing commercial research activity in Scotland

Steve McSwiggan
Deputy Director
Edinburgh CRF
Aims

- Describe Commercial Research in NHS Scotland
- Discuss Commercial Activity
- Describe Processes in Scotland
- Therapeutic areas
- Performance & Value
- Workshop- Enhancing commercial research activity in Wales
NHS Scotland

- Health and Care devolved to Scottish Government
- Covers 5.5m people
- 160,000 staff
- Unitary Health Boards cover both Primary and Secondary Care

Health Research is coordinated by the CSO, part of the Scottish Government

- CSO provides total funding of ~£50m per year to NHS Research Scotland to support and coordinate health research activity
- Health Research support is delivered by NHS Boards - RD&I - working together as NHS Research Scotland

National Infrastructure

**CENTRAL MANAGEMENT TEAM (NRS-CMT)**
National point of contact

**PERMISSIONS COordinating CENTRE**
Coordinated multisite approvals

**NETWORKS & SPECIALTY GROUPS**
26 Networks led by internationally recognised clinical academics

**SHARE**
300,000 registered interest to be contacted about clinical studies

Regional Infrastructure

**CLINICAL RESEARCH FACILITIES**
Dedicated clinical research space and expertise to support delivery of multidisciplinary clinical research.

**BIOREPOSITORIES**
Network of centres providing nationally co-ordinated access to human tissue samples

**DATA SAFEHAVENS**
Robust and secure access to NHS data

NHS Scotland
NHS Research Scotland

www.nrs.org.uk
@NHSResearchScot
The NRS Network

Dedicated Local Resource

- Each Board has an R&D contact providing a point of contact to facilitate, approve and support studies
- Resource is focussed at the main cities

Experienced National Research Leads

- All NHS research in Scotland is the responsibility of one of 26 NRS Research Networks.
- Each is led by a Scottish clinical academic who is a recognised expert in their field
- These dedicated national networks provide Scotland-wide advice and support for researchers

NHS Research Scotland
Single review model

- Single cost model in operation for nearly a decade
- One site carries out costing for all participating Scottish sites
- One site carries out multisite contract and study review for all participating Scottish sites
- We accept a UK review which has been carried out elsewhere in the UK – no duplication

Scotland wide coordination

- Central Feasibility System
  - Single CDA
  - Single point of contact for site ID and feasibility handling
  - Managed responses
- Central Management Team
  - National point of contact
  - Issue resolution
  - Activity monitoring and performance management with Boards and Networks
- National metrics and Performance Management
  - Detailed breakdowns by site and Specialty
Working across the UK

Scotland works with partners to deliver the UK-wide system

- Unified Research Ethics System
- Common Research Governance Framework
- Use standard IRAS application route for REC and R&D approval
- Permissions Coordinating Centre in Aberdeen distribute approval requests
- Single system for UK and NRS Study Wide Reviews (SWR - previously called “Generic Review”)

Scotland works to UK standards

- Use standard UK contract templates without modification
- Use standard Industry Costing Template (iCT)
- Use standard tariffs agreed through NIHR Commercial Costing Reference Group
- Work with and recognise other UK initiatives
  - Combined Review Process
  - Industry Licensing Access Pathway
NRS has delivered single contract and cost reviews for nearly a decade

- Experienced reviewers
- Working processes are in place

The UK is implementing a single National Contract Value Review (NCVD)

- UK wide programme of work
- Primary work is through NHS E/I, HRA, NIHR to develop single costing process in England
- NRS support the development of a single UK-wide process to simplify costing and streamline study start-up

NRS will continue to deliver a single Scottish costing

- Evolutionary changes to contacts and process
- Works within the UK framework

Working with NIHR to align process and systems

- Details of cost statement handling and information flow
Activity and Recruitment

Recruitment (FY)

Studies opened (FY)

Commercial

Non-Commercial

NHS Research Scotland

www.nrs.org.uk  @NHSResearchScot
Commercial New Study Sites Opened

FY14/15 to FY22/23

* Half year data
Commercial Recruitment Trend

FY14/15 to FY22/23

* Half year data
Feasibilities
## 2022 Feasibility Summary

### Early Feedback Site Intelligence Site Identification Total

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### Site ID Responses

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<td>Yes</td>
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### Funder Studies

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<td>440</td>
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<tr>
<td>Non-Commercial</td>
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Feasibility Therapy Areas

Top 6 Therapy Area Requests

- Cancer: 155
- Children: 42
- IDM: 30
- Dermatology: 28
- NDN: 23
- MSK: 21

Top 6 Therapy Area Responses

- Cancer: 34
- Dermatology: 12
- IDM: 12
- NDN: 11
- Children: 10
- Respiratory: 9
Feasibility Declines

Reasons for Decline

- No support department capacity: 513
- No response from local investigator: 276
- PI does not have time to lead the study: 268
- Insufficient patient population: 260
- Lack of capability - do not have necessary equipment/facility: 214
- Patients not treated locally - they would be referred to another facility: 214
Studies/Sites
Active Commercial Phases (Feb 2023)

![Bar Chart showing the distribution of studies by phase and type]
Recruitment
Commercial Orderbook

- Study Sites
- Total Contract Price

Year to date

FY14-15: £13.3M
FY15-16: £16.7M
FY16-17: £19.7M
FY17-18: £17.2M
FY18-19: £18.6M
FY19-20: £20.8M
FY20-21: £29.1M
FY21-22: £29.5M
FY22-23: £18.2M

NHS Research Scotland

www.nrs.org.uk   @NHSResearchScot
Local Solutions- Edinburgh CRF

- Three MHRA accredited phase 1 units
  - 75 NHS Staff
  - 100+ active studies – all phases and types
  - 50+ new studies a year
  - Constant stream of requests for SSVs and EOIs

- CRF resource video and tour
- CRF resource catalogue
- Single co-ordinator nurse with deputy for studies
- Site set up study expectations document
- SIV’s only when Sponsor Green Light expected within 24-48 hours
Workshop focus thoughts

- Why do commercial studies
- Building constructive relationships with Industry
  - Building Trust
  - Strategic priorities
  - Enablers and barriers
- Staffing and resources
  - Income prediction and contracts
- Changing the dynamic
  - Partnerships or customers?
Workshop Activity: Part 1: Mind Map

• Focus on **connections** that have to be made to get a study up, running and delivering efficiently at site

• **What the perspective/focus of NHS staff are**
  • e.g. PI, Nurses/CRPs, Labs, Imaging, R&D, Contracts.

• **Flip it for Commercial Sponsor**
  • Sponsor, CRO, eg Feasibility Teams, contract teams, kick off staff, IVRS, Monitors, 3rd party vendors.

• **Suggestions on how NHS site staff can take responsibility for this process**
  • having right conversations, with the right people at the right time, so that we are ready to run once R&D have confirmed C&C and site is initiated.

• **Aim is to help us understand Industry vs NHS expectations better to disseminate this more widely post conference**