

Enhancing commercial research activity in Scotland

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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**

Infrastructure Overview



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

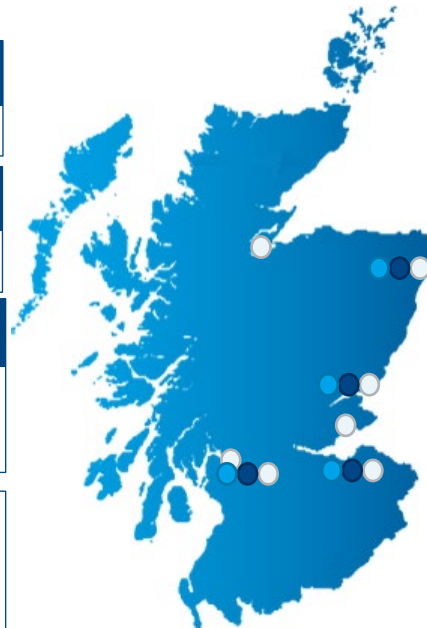
Coordinated multisite approvals

NETWORKS & SPECIALTY GROUPS

26 Networks led by internationally recognised clinical academics



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 SAFE HAVENS

Robust and secure access to **NHS data**

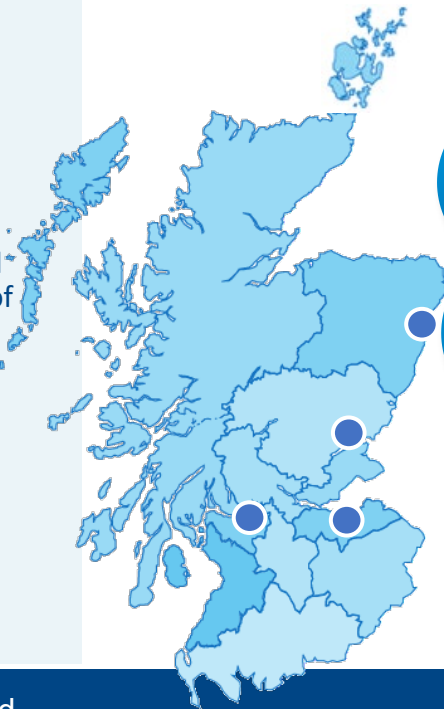
The NRS Network

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



One 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

Single Cost Review

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

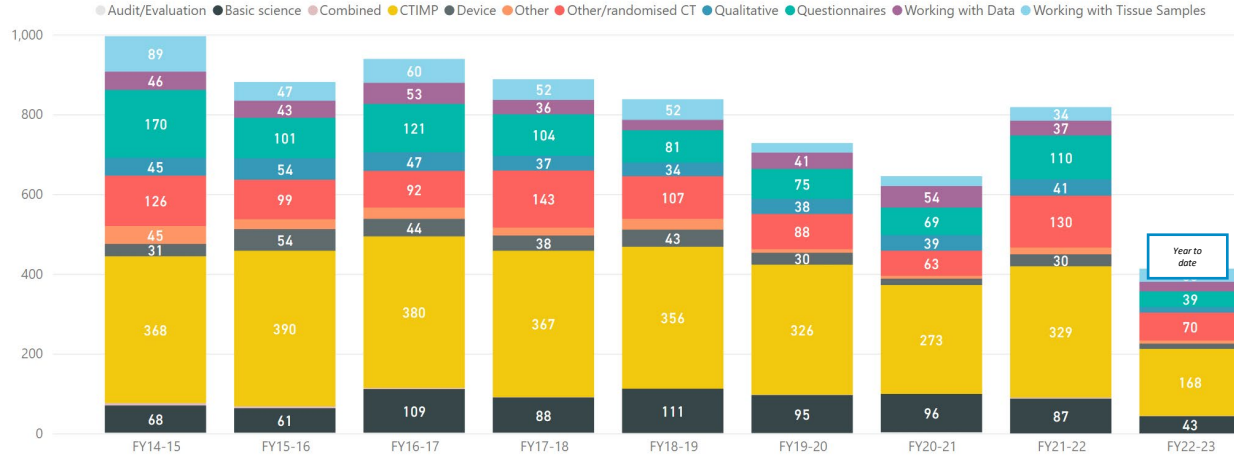
- Evolutionary changes to contracts and process
- Works within the UK framework

Working with NIHR to align process and systems

- Details of cost statement handling and information flow

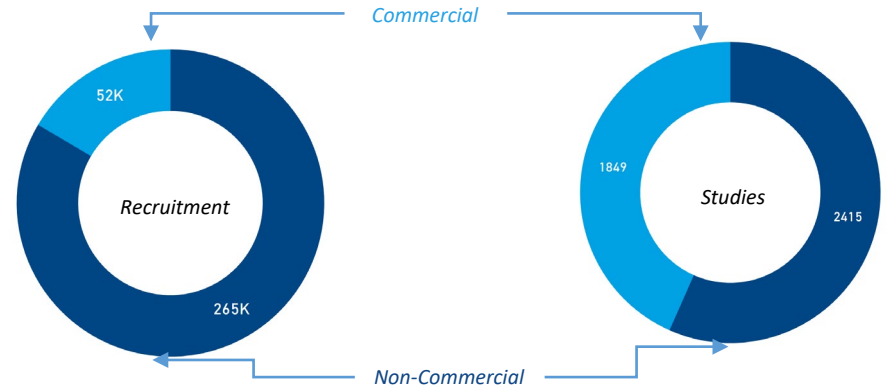
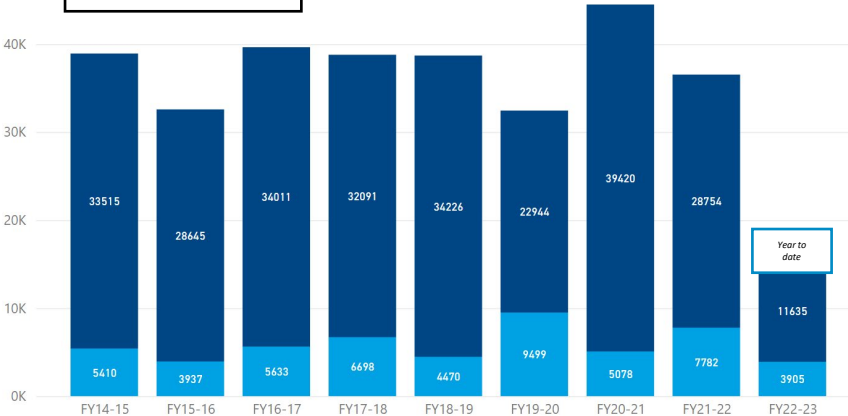
Activity and Recruitment

Studies opened (FY)



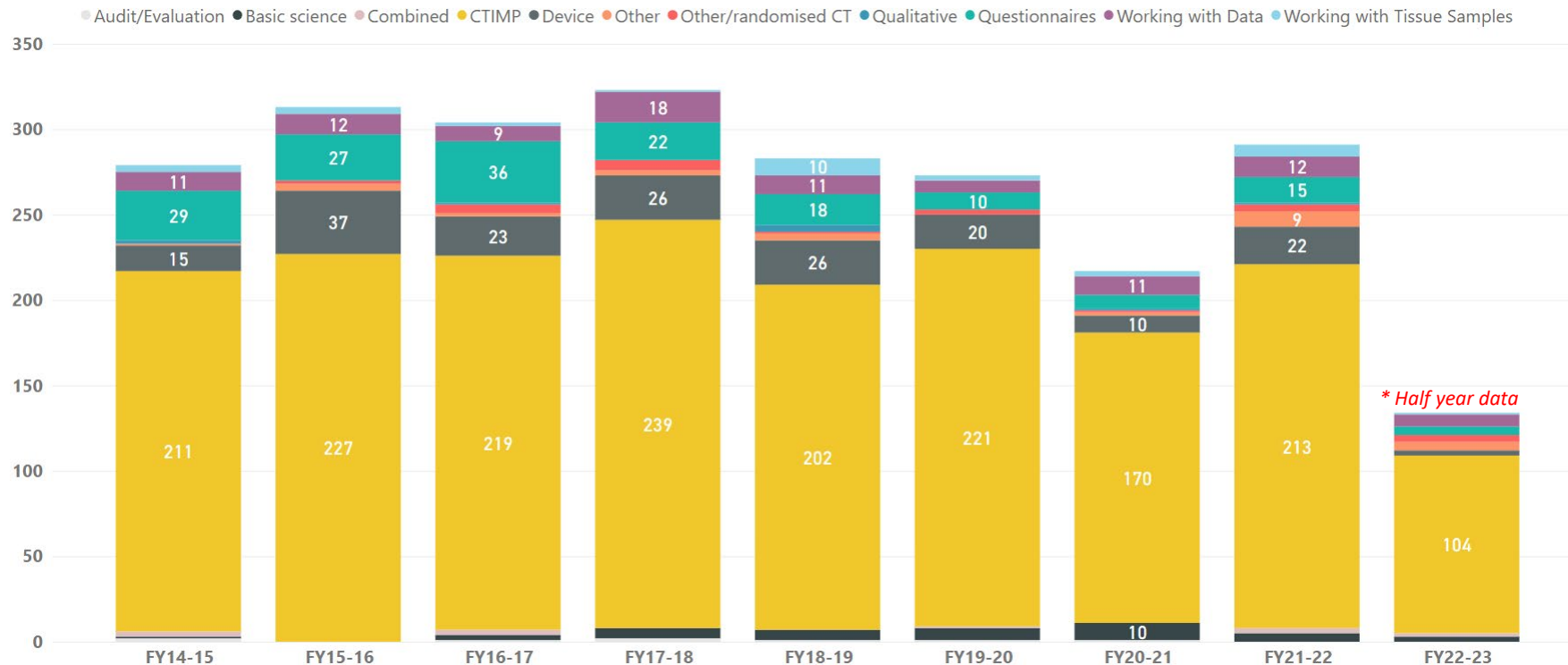
Recruitment (FY)

● Commercial ● Non Commercial



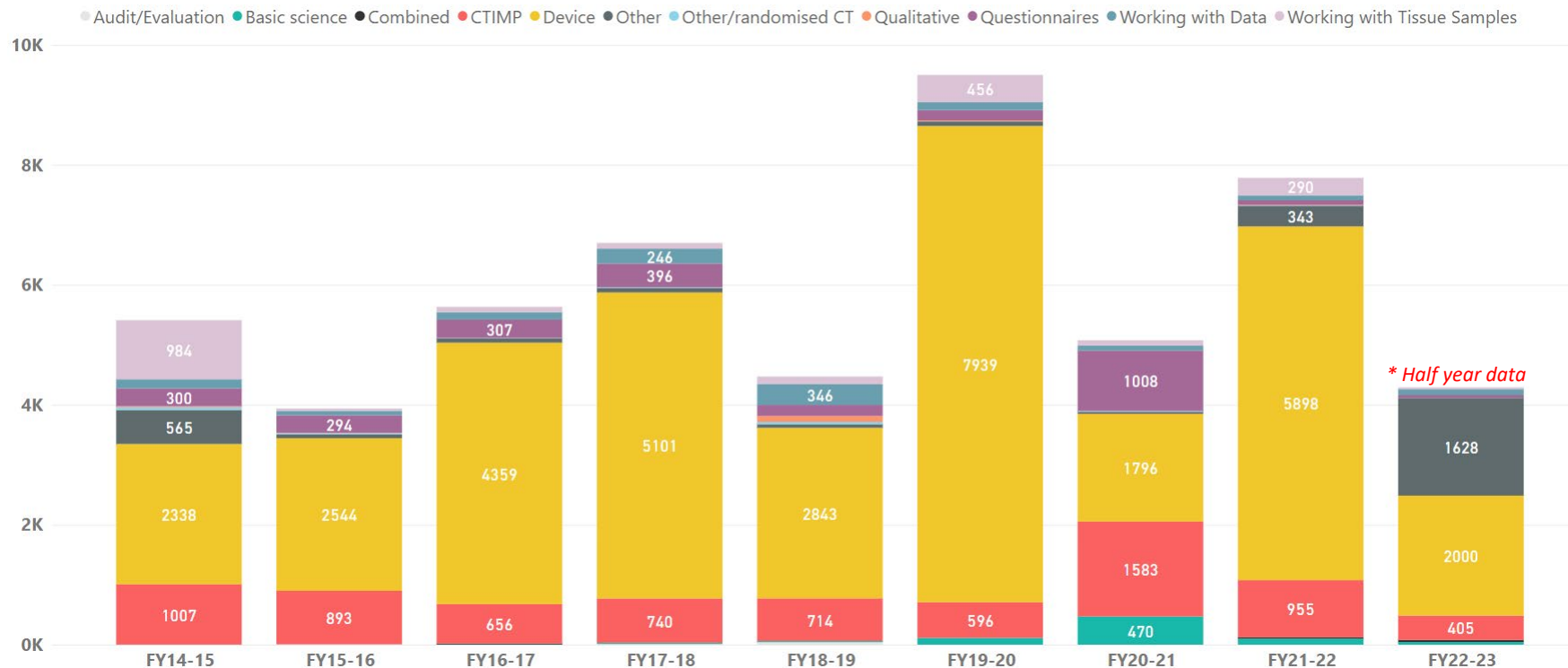
Commercial New Study Sites Opened

FY14/15 to FY22/23



Commercial Recruitment Trend

FY14/15 to FY22/23



Feasibilities

2022 Feasibility Summary

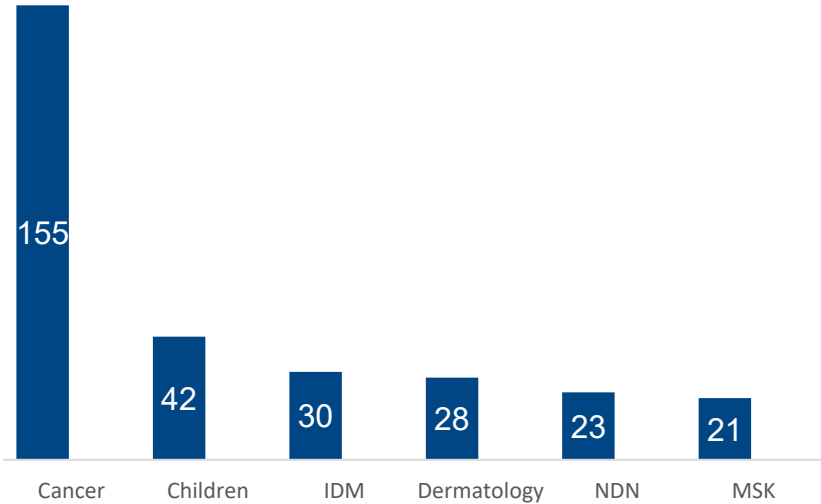
EARLY FEEDBACK	SITE INTELLIGENCE	SITE IDENTIFICATION	TOTAL
8	4	457	469

Site ID	Responses
Yes	163
No	294

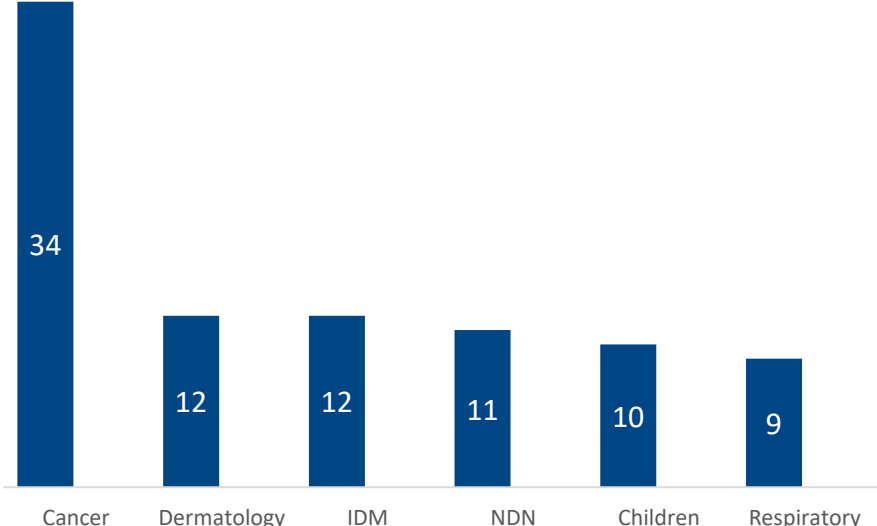
Funder	Studies
Commercial	440
Non-Commercial	29

Feasibility Therapy Areas

Top 6 Therapy Area Requests

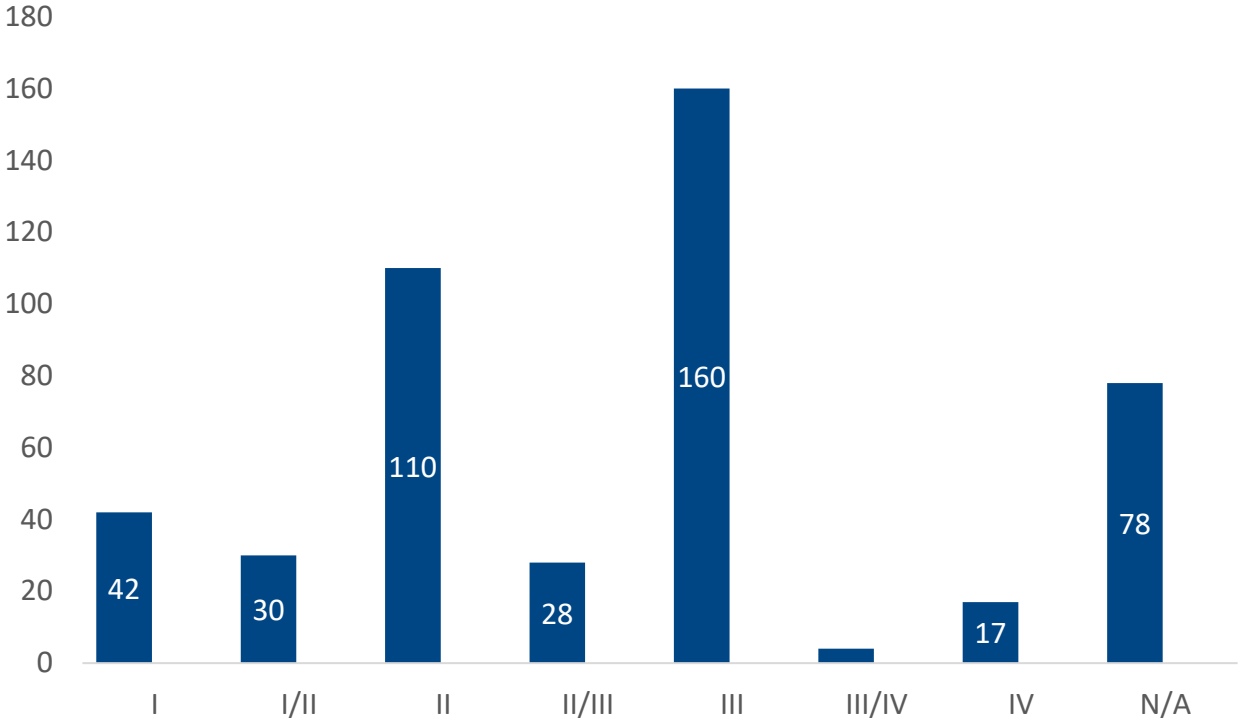


Top 6 Therapy Area Responses



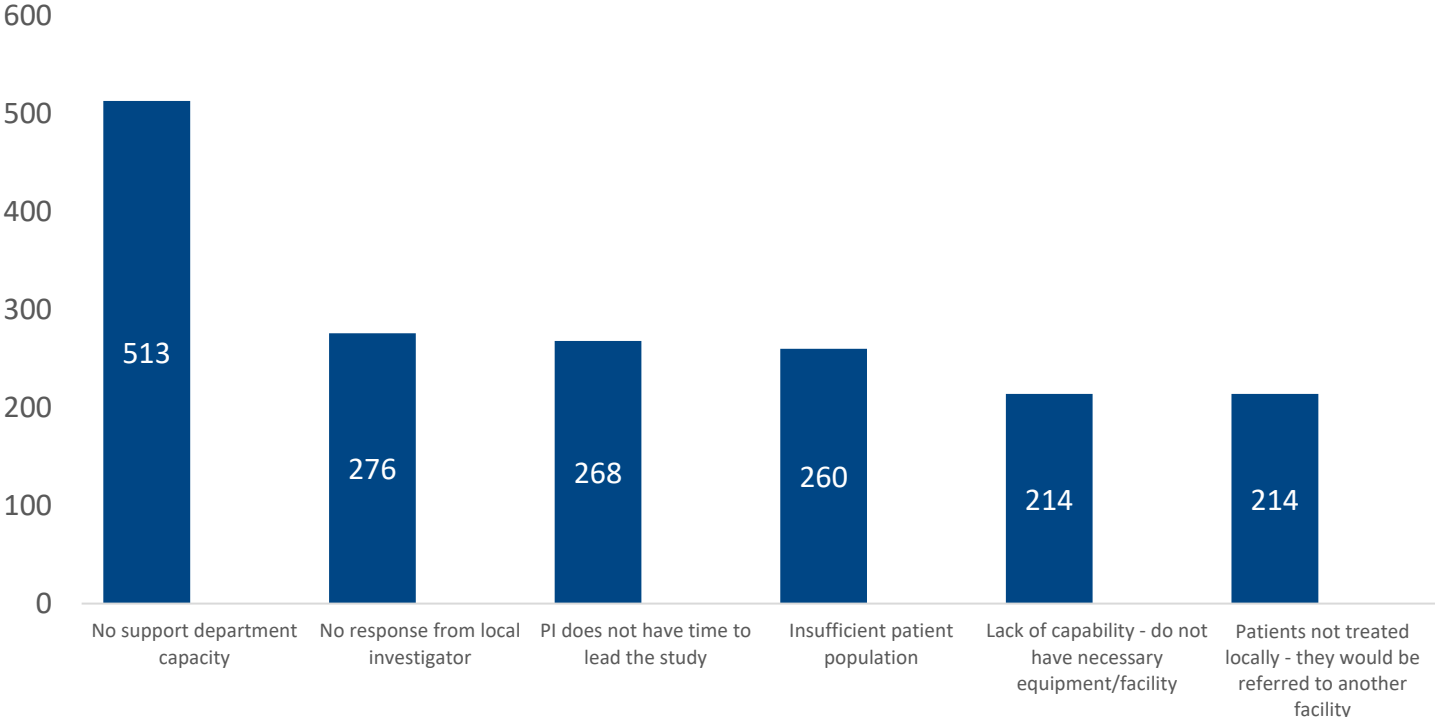
Feasibility Trial Phases

Trial Phases



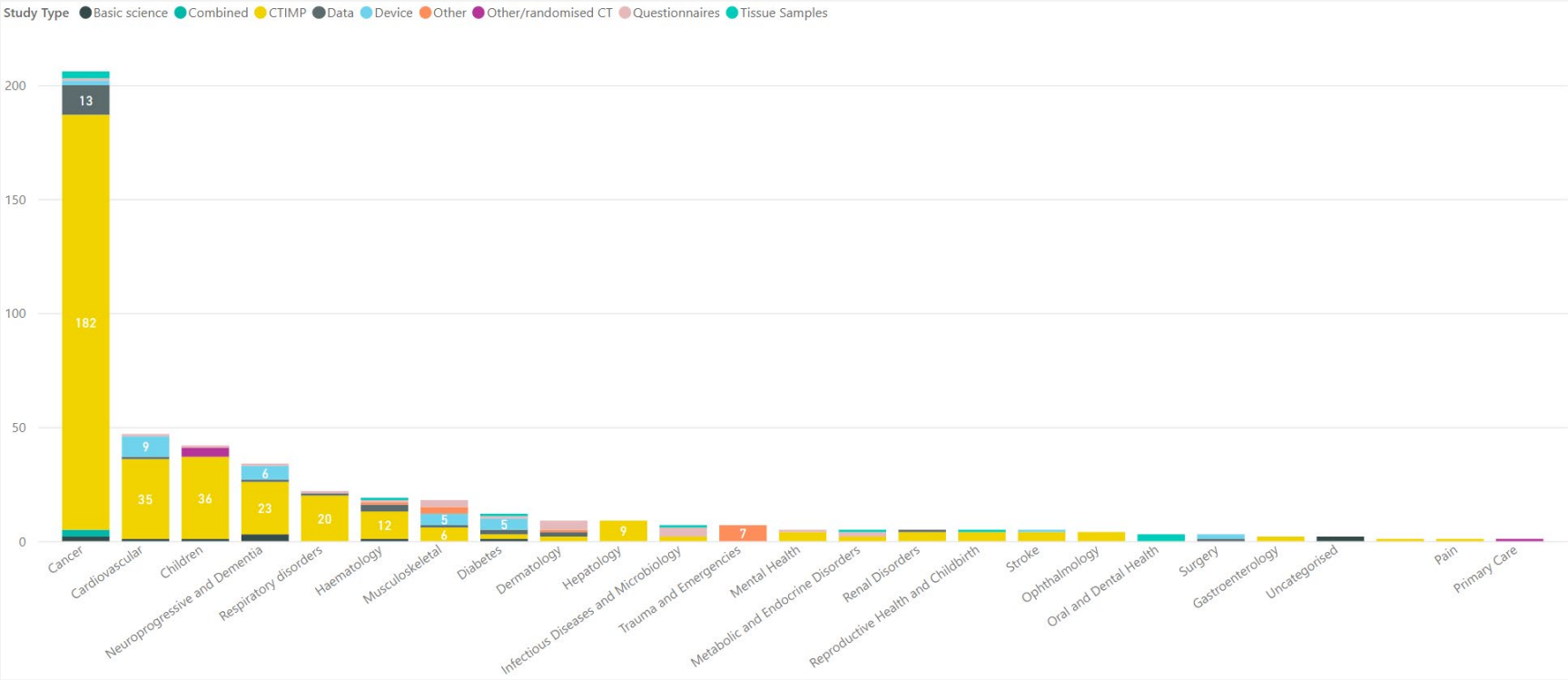
Feasibility Declines

Reasons for Decline

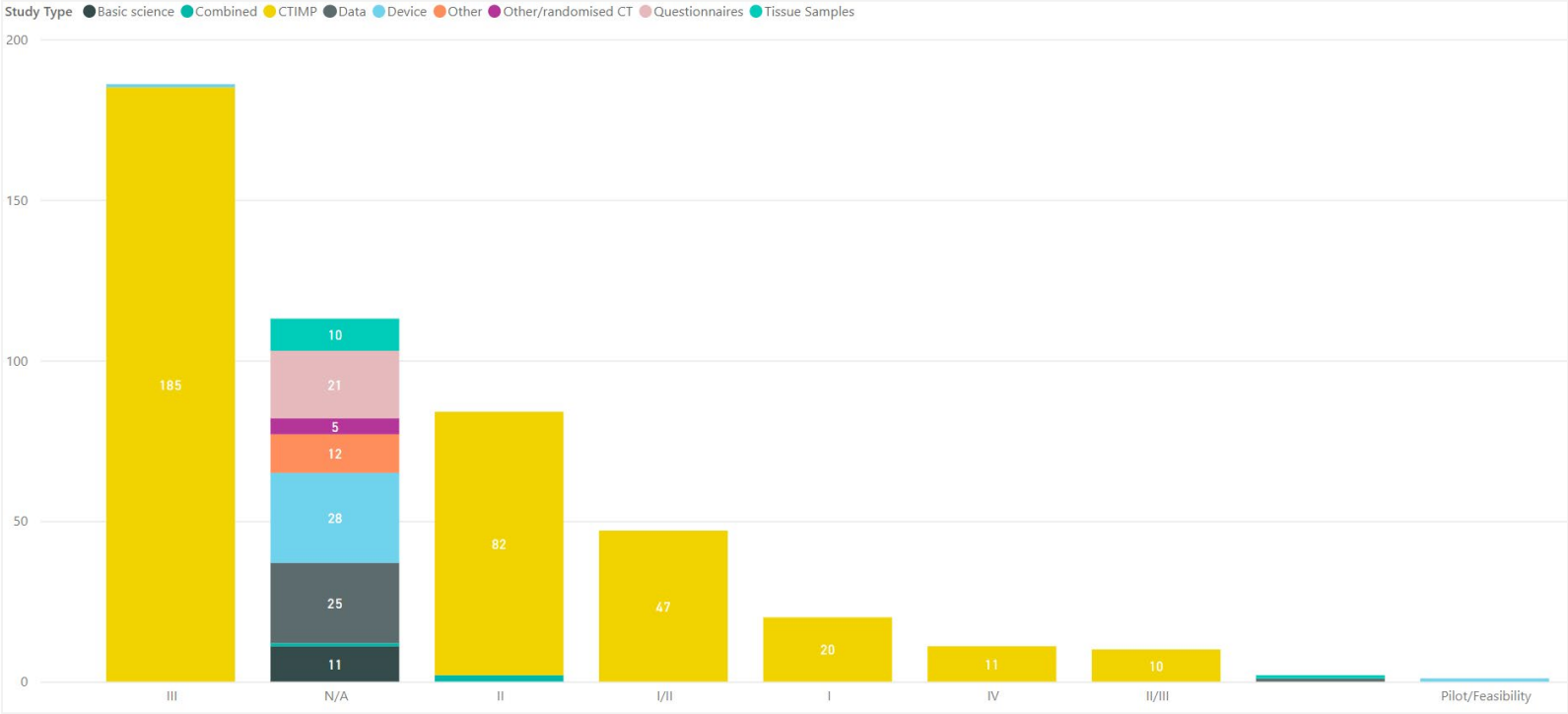


Studies/Sites

Active Commercial Studies (Feb 2023)

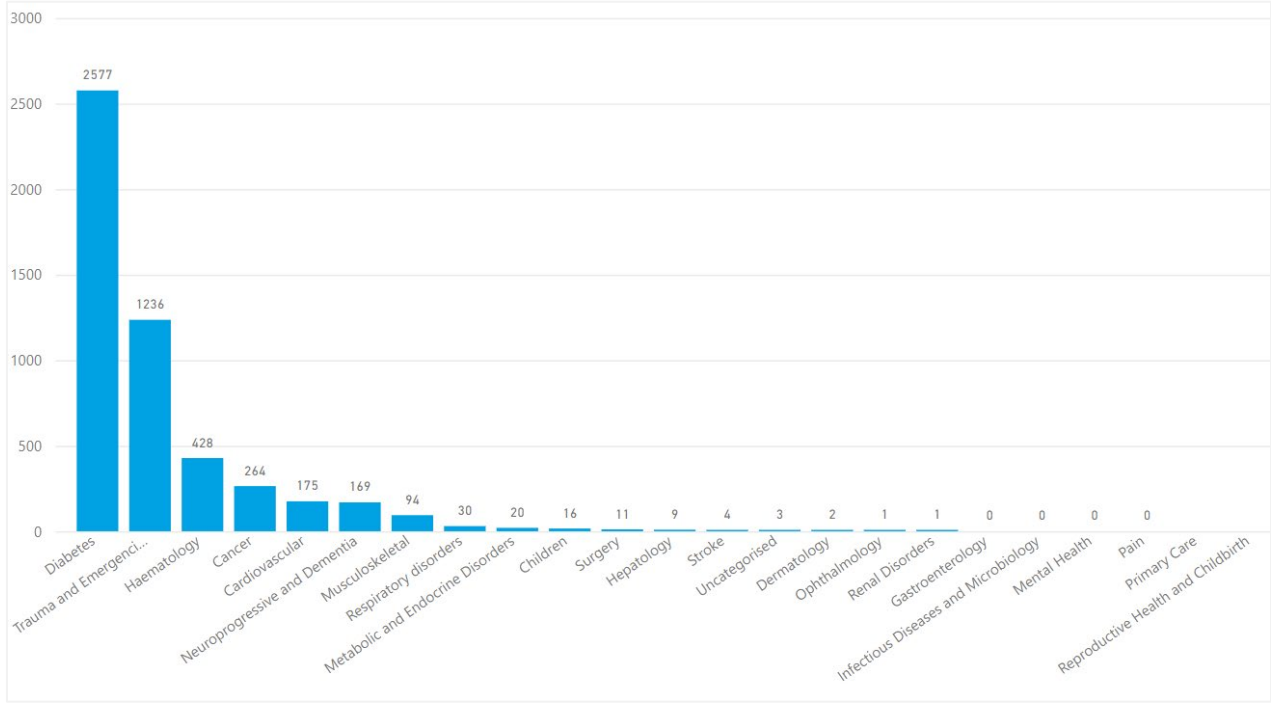


Active Commercial Phases (Feb 2023)

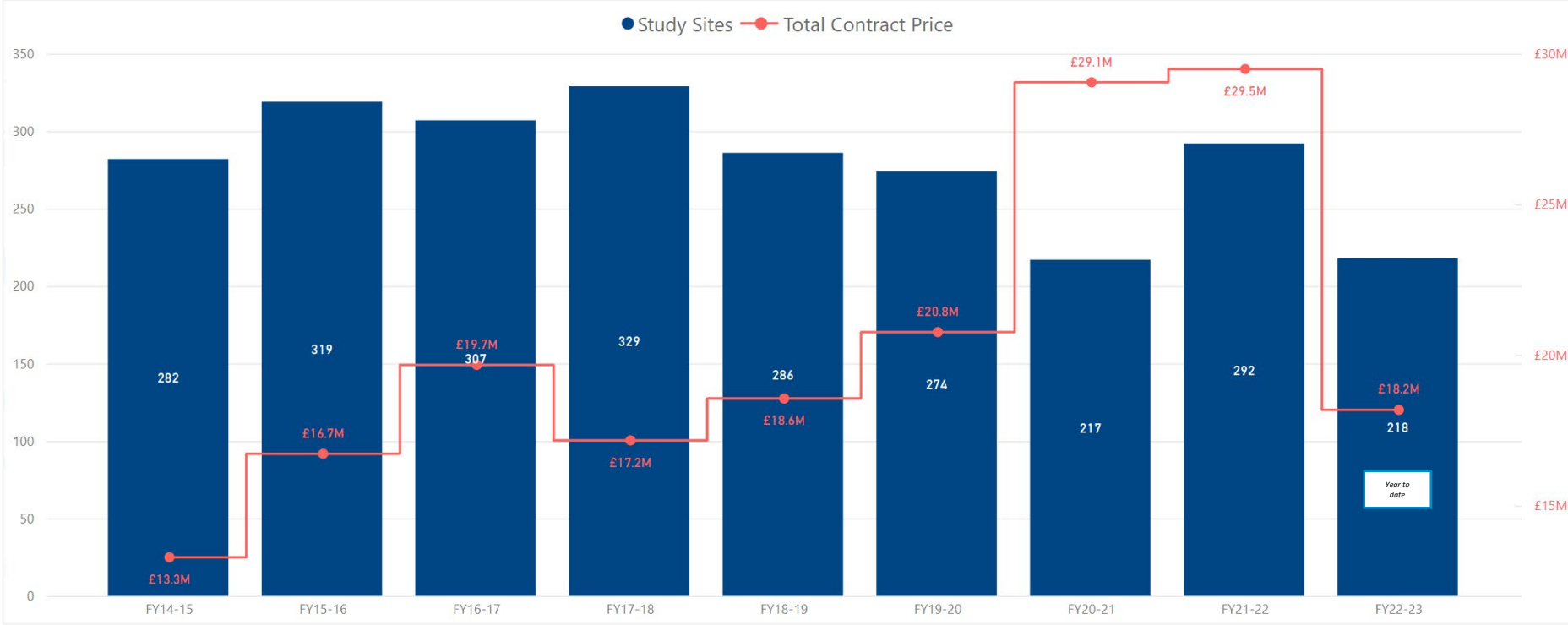


Recruitment

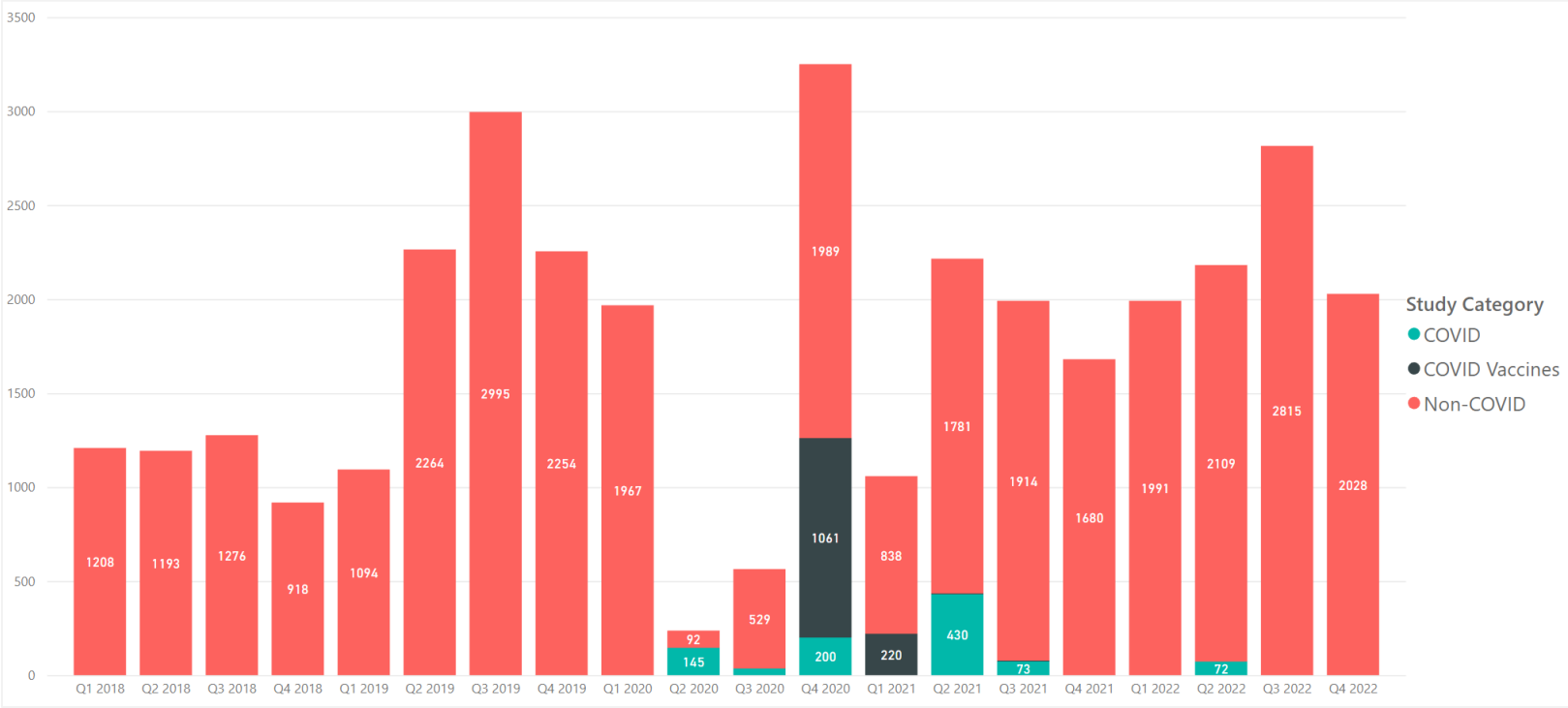
Commercial Recruitment (Oct 21-Sep 22)



Commercial Orderbook



Commercial COVID Recruitment



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



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