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ICHT Divisional Research Management

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- Dr Paul Craven, Head of Clinical Research Operations

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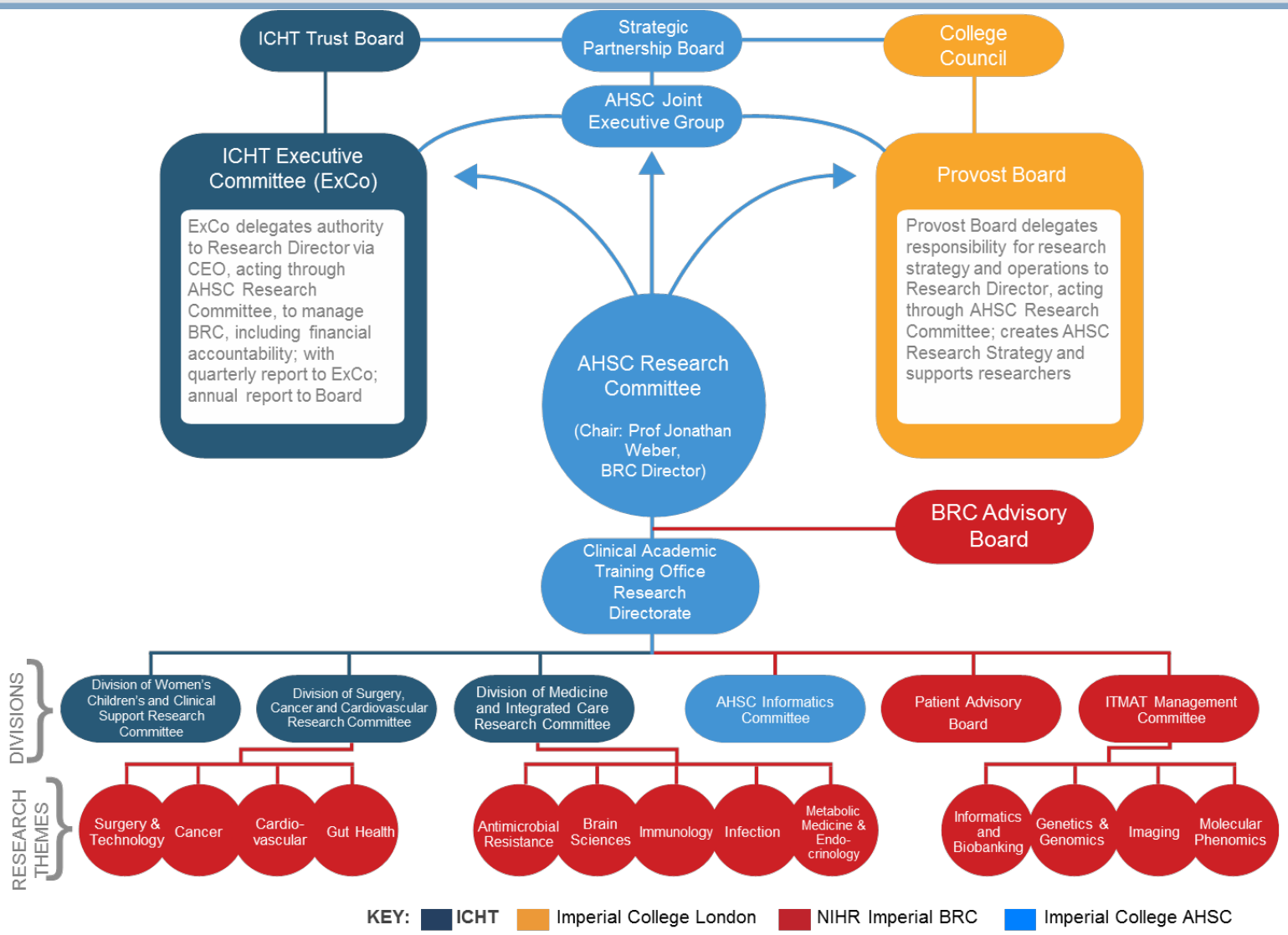
Overall R&D Governance across Imperial AHSC



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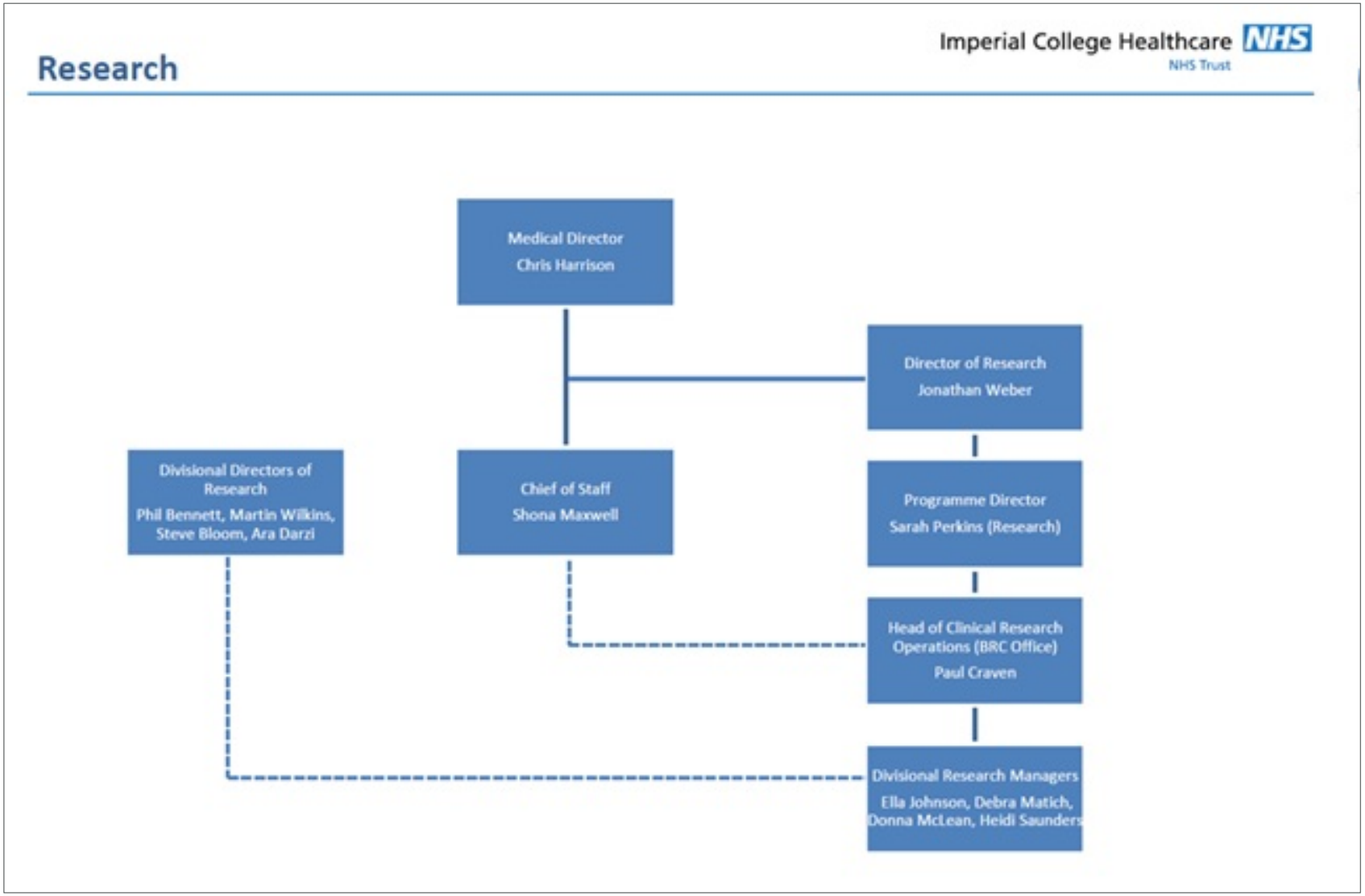
R&D Governance in ICHT



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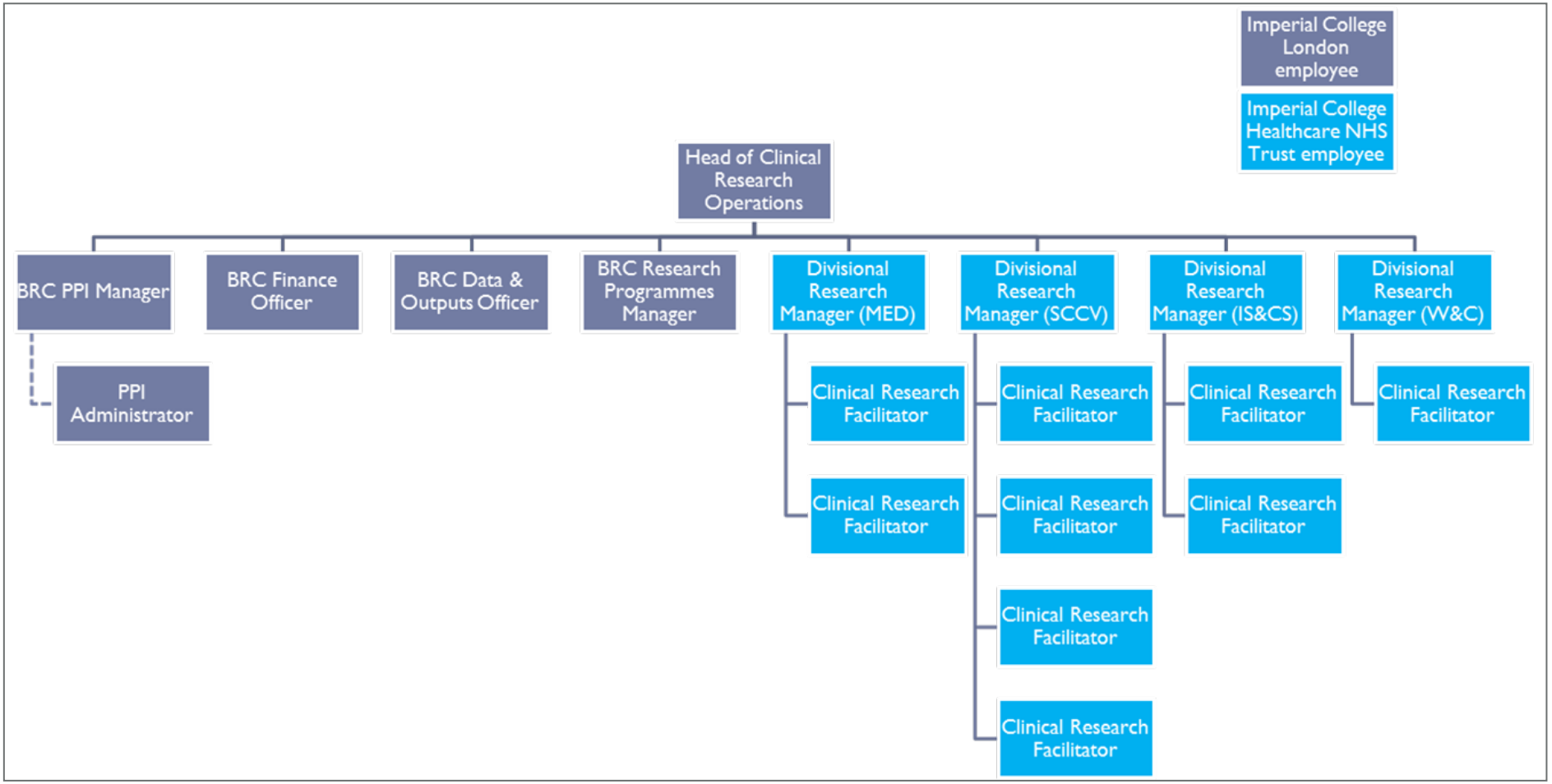
Joint Working Across NHS and University: Clinical Research Operations Office



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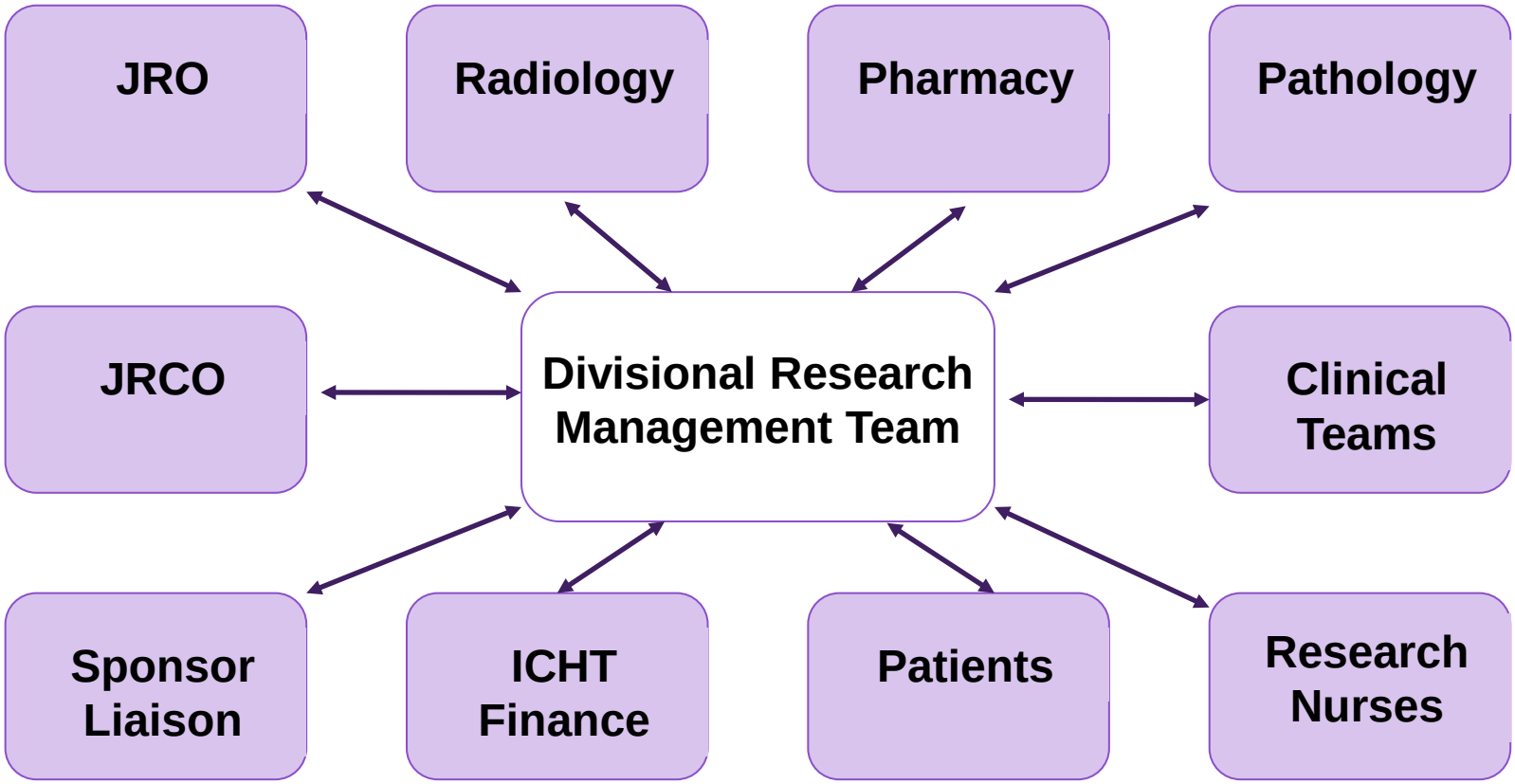
Divisional Research Management: Study Feasibility



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Study Feasibility Assessment – Can We Deliver?

- Protocol review and ‘local translation’
- Do we want to do the study?
- Targets – can we recruit enough patients in time?
- Patient flows – numbers / eligibility (committee review)
- Pharmacy/radiology/pathology – can they support the study?
  - Equipment
  - Resource
- Trial management – consultant time / research nurse
- Can we afford it? Cost negotiation.
- Patient benefit – access to new devices / diagnostics / drugs

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NHS R&D Funding Streams

NIHR Imperial BRC: £22.6m per annum

- Experimental medicine (translational of fundamental science into clinic)
- Competitive process; 5 year progamme
- Theme-based funding + central calls and other schemes (training)
- Supports infrastructure (tissue bank, genomics, molecular phenotyping, bioresources, informatics, ICTU, etc.)

NIHR Clinical Research Network (North West London): £3.5m p.a. approx.

- Supports high-quality clinical research in the NHS
- Activity-based (patient recruitment)
- Annually awarded through regional networks
- Internal allocation processes

Commercially-sponsored trials: £5m p.a. approx.

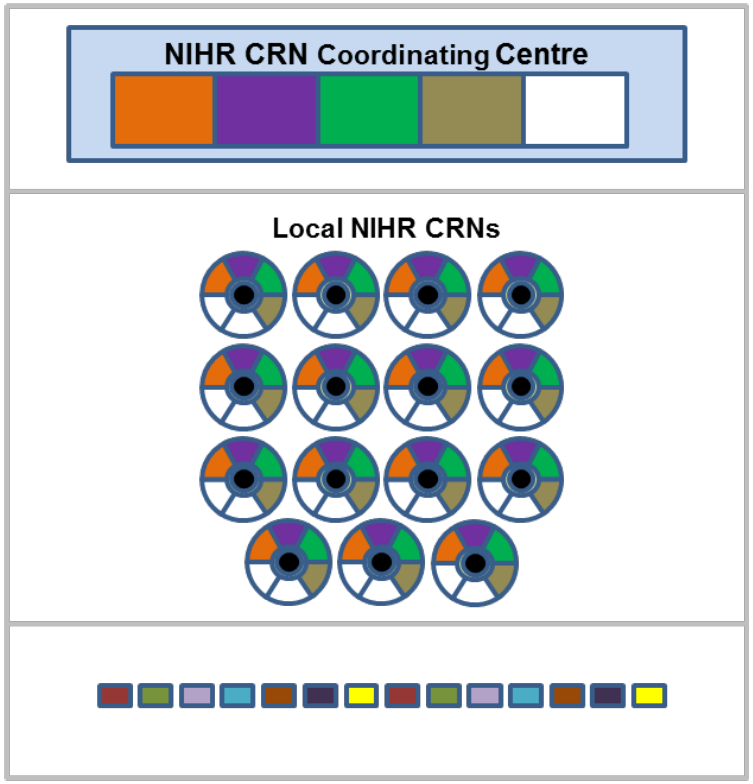
- Contract research
- Legal/management responsibility taken on by sponsor
- Standard contract and costing mechanisms

NWL Clinical Research Network

An integrated area-based model

15 Local Clinical Research Networks in operation from April 2014

- Mapped to Academic Health Science Network boundaries
- One host organisation per area
- Hosts will work to an operating framework setting out functions and responsibilities
- 5 year contracts, with one year operational plans



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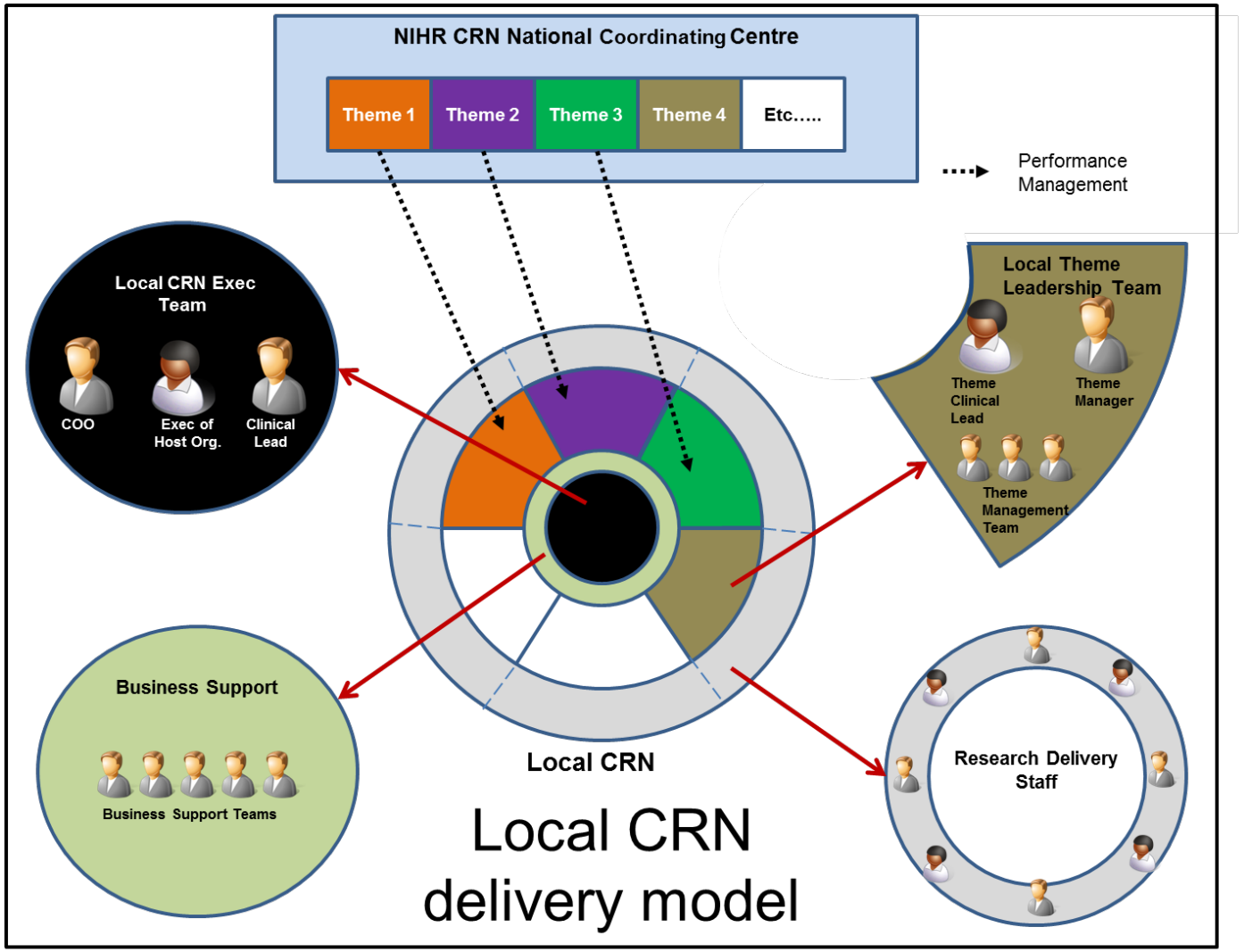
NWL Clinical Research Network



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NWL CRN: Performance Metrics Dashboard

Data up to 29 February 2016, as reported on 6 April 2016
CSP data as at 6 April 2016

NHS National Institute for Health Research
Clinical Research Network

Performance Report: CRN: North West London
February 2016

Objectives (all objectives relate to NIHR Portfolio studies)		North West London Measure	NWL Local Targets: Target	NWL Local Targets: Performance	National Measure (see note): NWL performance	National Measure (see note): National performance
1	Increase the number of participants recruited	Number of participants recruited in a reporting year	24,168 *26,374 FY*	102%	92% *28,989**	91%
2	Increase the proportion of studies recruiting to time and target	Proportion of **open commercial** study sites recruiting to time and target	80%	28%	17%	32%
		Proportion of **closed commercial** study sites that recruited to time and target	80%	50%	47%	58%
		Proportion of **open non-commercial** study sites recruiting to time and target	80%	44%	28%	29%
		Proportion of **closed non-commercial** study sites that recruited to time and target	80%	50%	61%	72%
3	Increase the number of commercial contract studies delivered through NIHR CRN	Number of commercial contract studies recruiting in a reporting year	138 *150 FY*	103%	N/A	TBC
4	Reduce the time taken for eligible studies to achieve NHS Permission through CSP	Proportion of study-wide CSP reviews completed within 15 calendar days	80%	99%	99%	72%
		Proportion of local CSP reviews completed within 15 calendar days	80%	87%	87%	81%
5	Reduce the time taken to recruit first participant**	Proportion of **commercial** study sites recruiting the first participant within 30 days of NHS Permission	80%	N/A	75%	60%
		Proportion of **non-commercial** study recruiting the first NWL participant within 30 days of first NWL NHS Permission	80%	26%	35%	44%
6	Increase NHS participation into NIHR CRN Portfolio studies	Proportion of NHS Trusts recruiting each year into NIHR studies	100%	100%	100%	99%
		Proportion of NHS Trusts recruiting each year into commercial contract studies	70%	70%	67%	72%
		Proportion of General Medical Practices recruiting each year	25%	19%	19%	41%
7	Increase recruitment to Dementias and Neurodegenerative (DeNDRoN) studies	Number of participants recruited into DeNDRoN studies	290 *309 FY*	275%	275%	259%

Notes: The national measures differ slightly from the NWL measures shown above.
* North West London aspirational target; ** National Measure figures taken from Q3 HLO data cut

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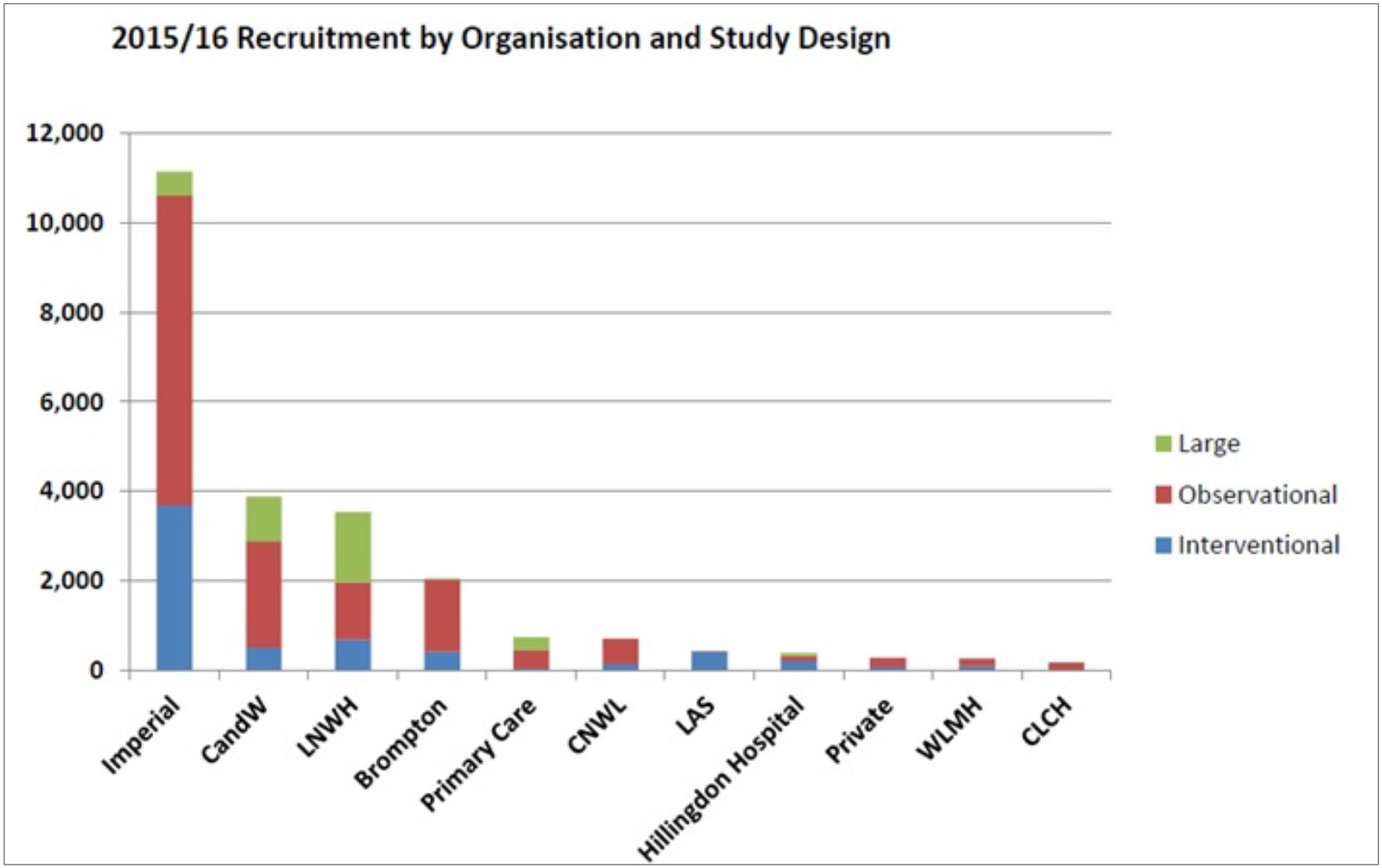
ICHT Performance in NWL CRN



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Commercial Contract R&D Studies

- Pharma / medtech contracts with one or more NHS sites
- Legal responsibility for design and conduct of study lies with external commercial organisations (‘sponsorship’)
- ICHT acts as a site to recruit participants and carry out study according to protocol (‘to time & target’)
- Any IP developed is owned by the sponsor
- Model contract agreements and costing templates used
- ICHT costs are covered in full
- 70% overhead (o/h) rate added (corporate)
- 20% capacity-building (c/b) rate also added

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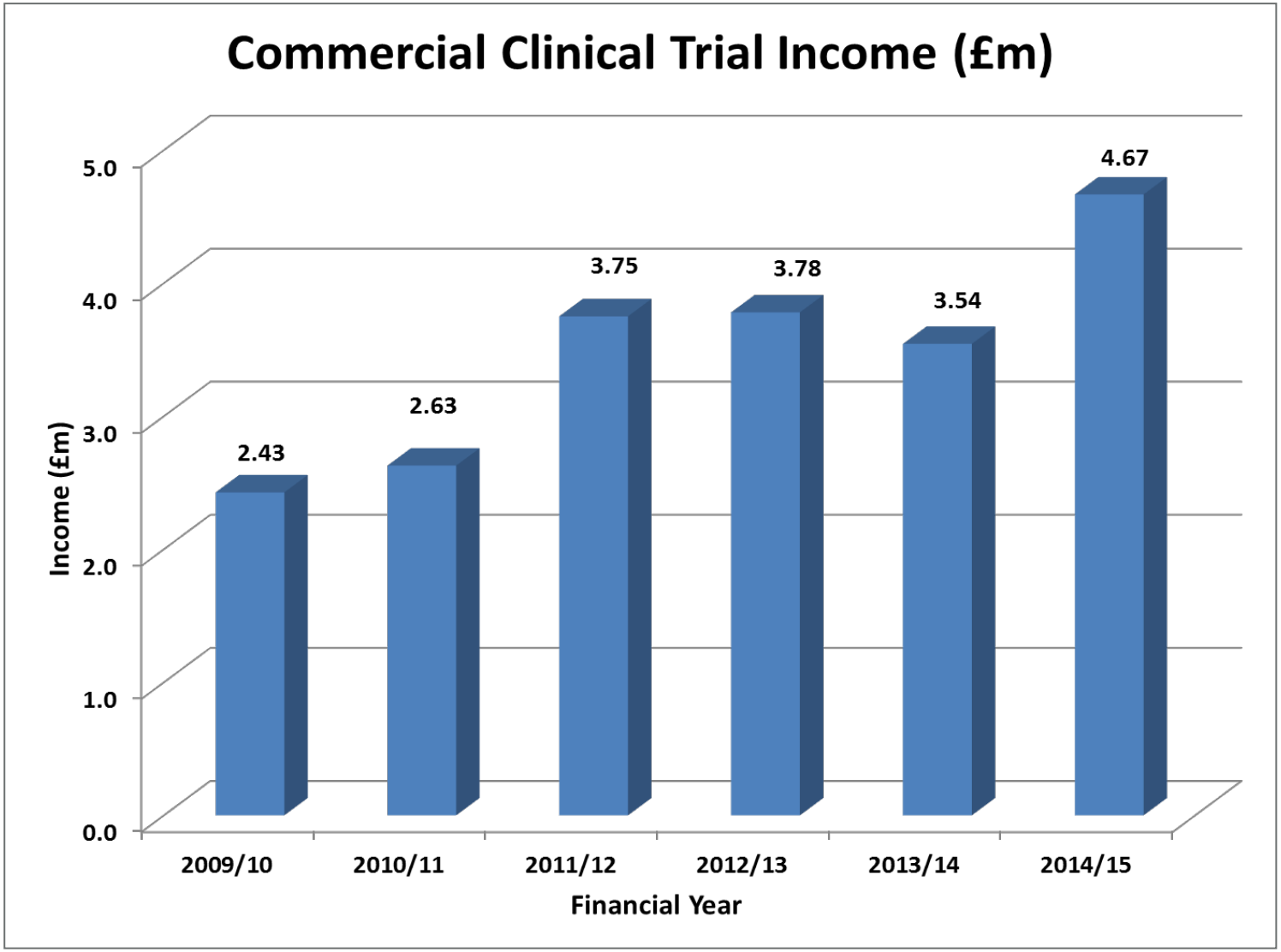
Commercial Trials Income



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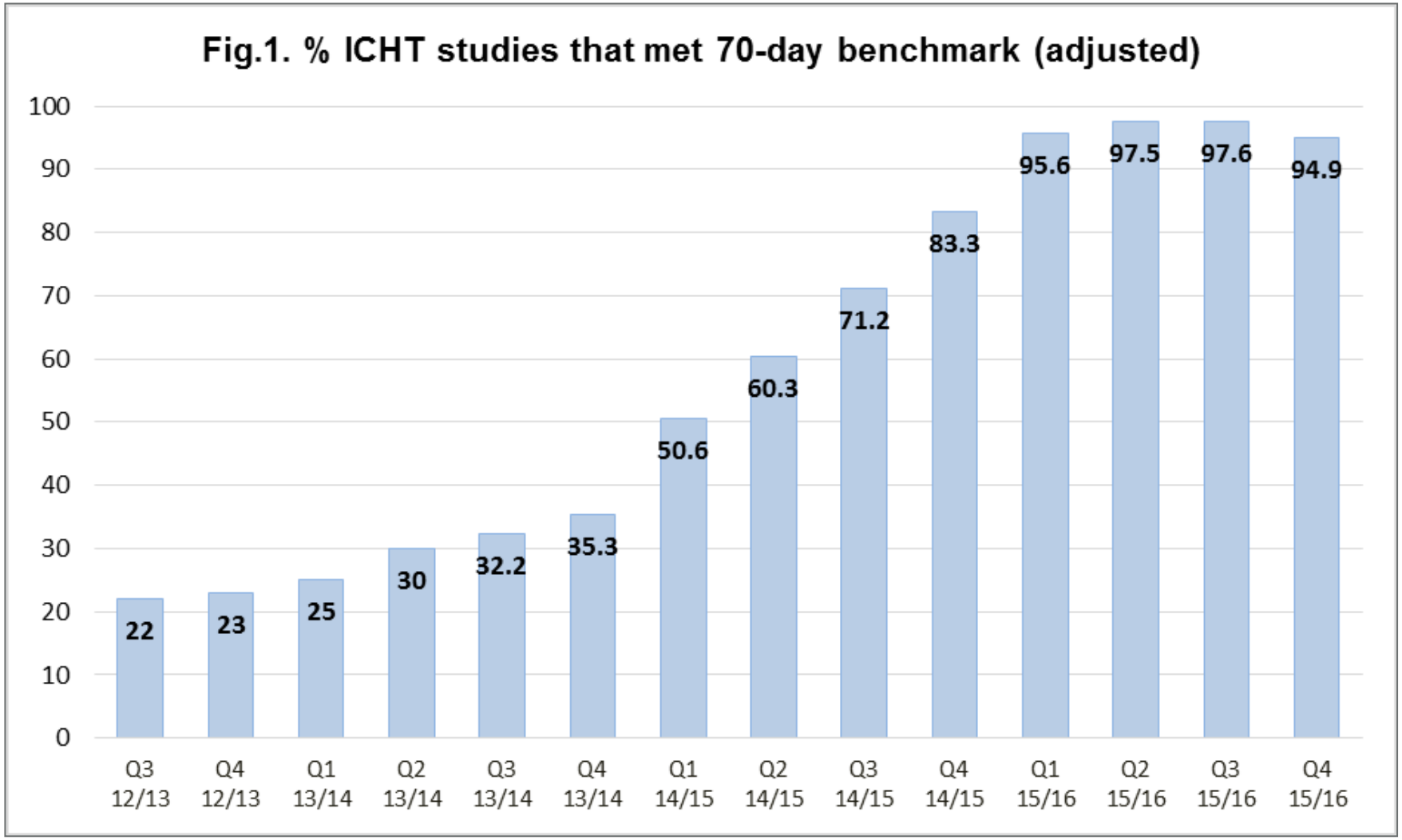
NIHR Performance Metrics: Initiation



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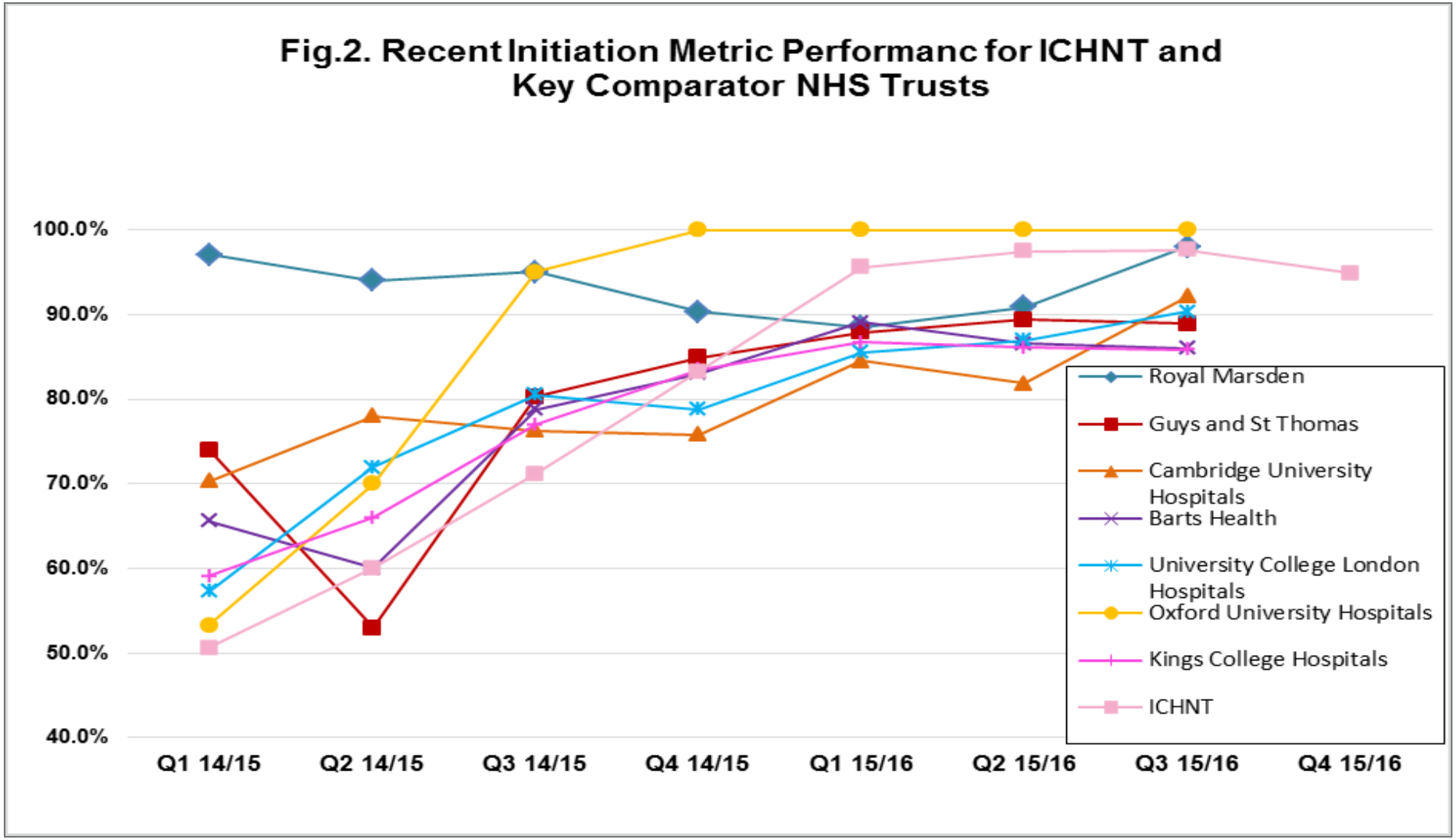
NIHR Performance Metrics: Initiation



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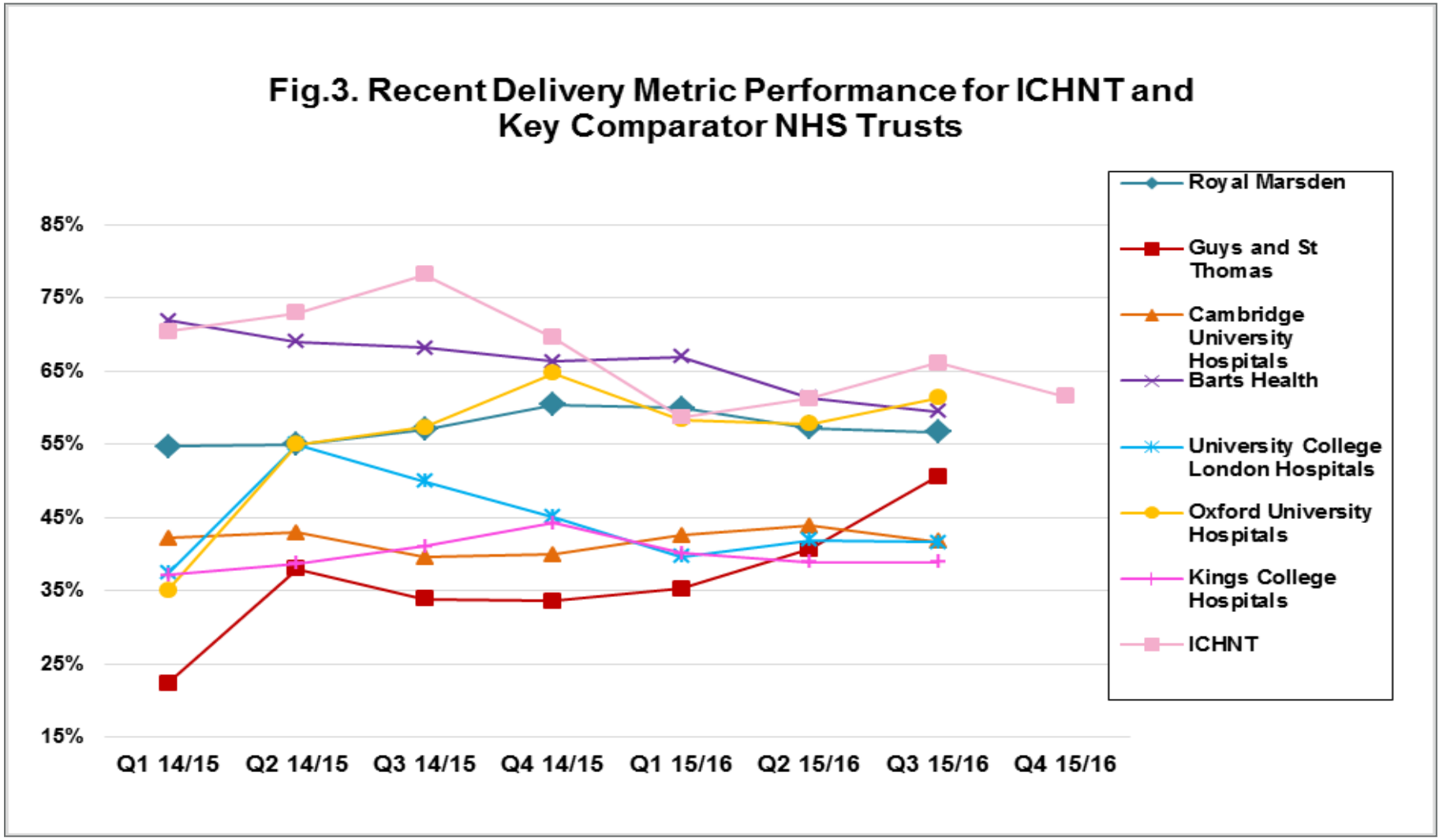
NIHR Performance Metrics: Delivery



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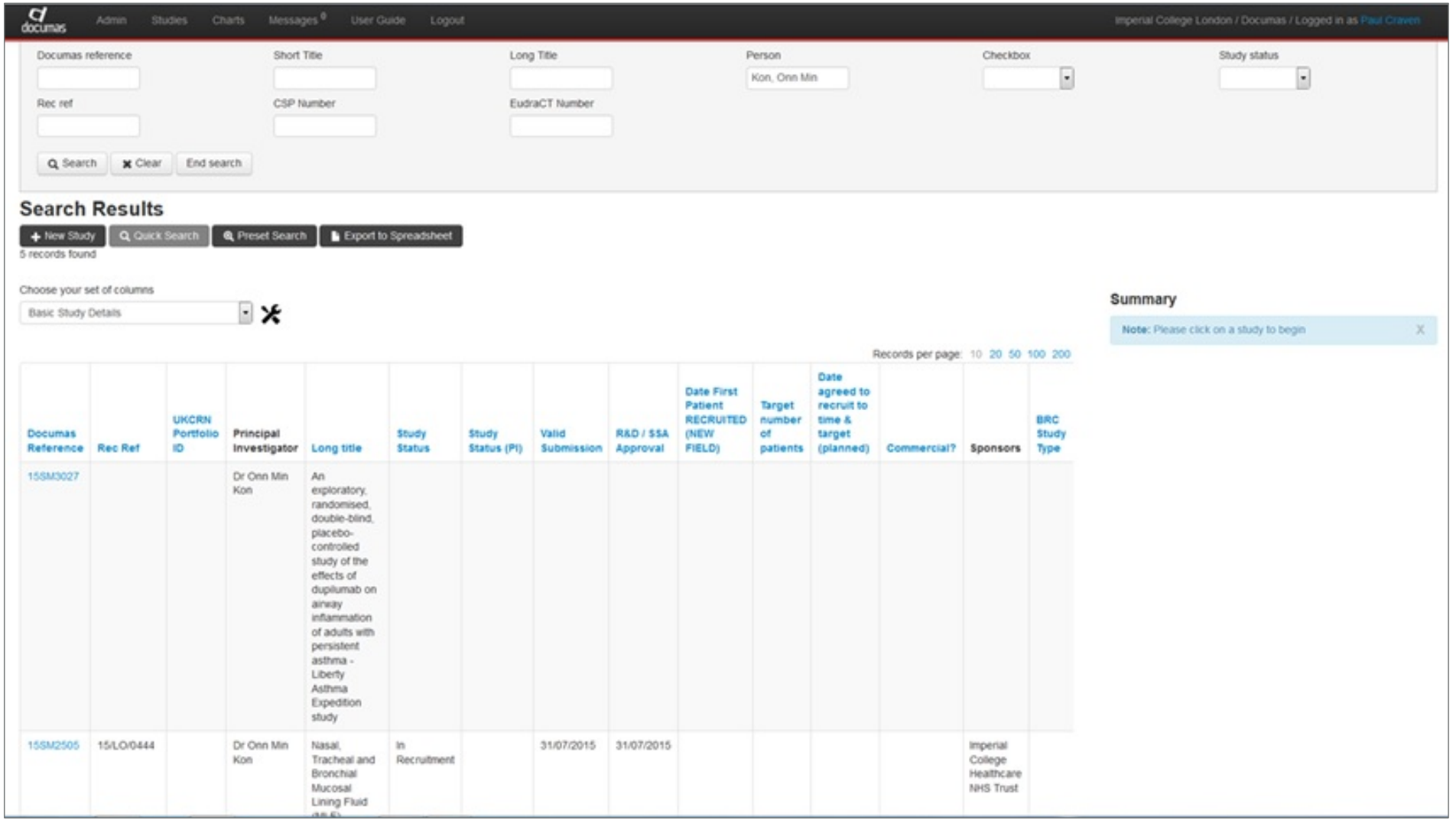
DOCUMAS Clinical Trials Management System



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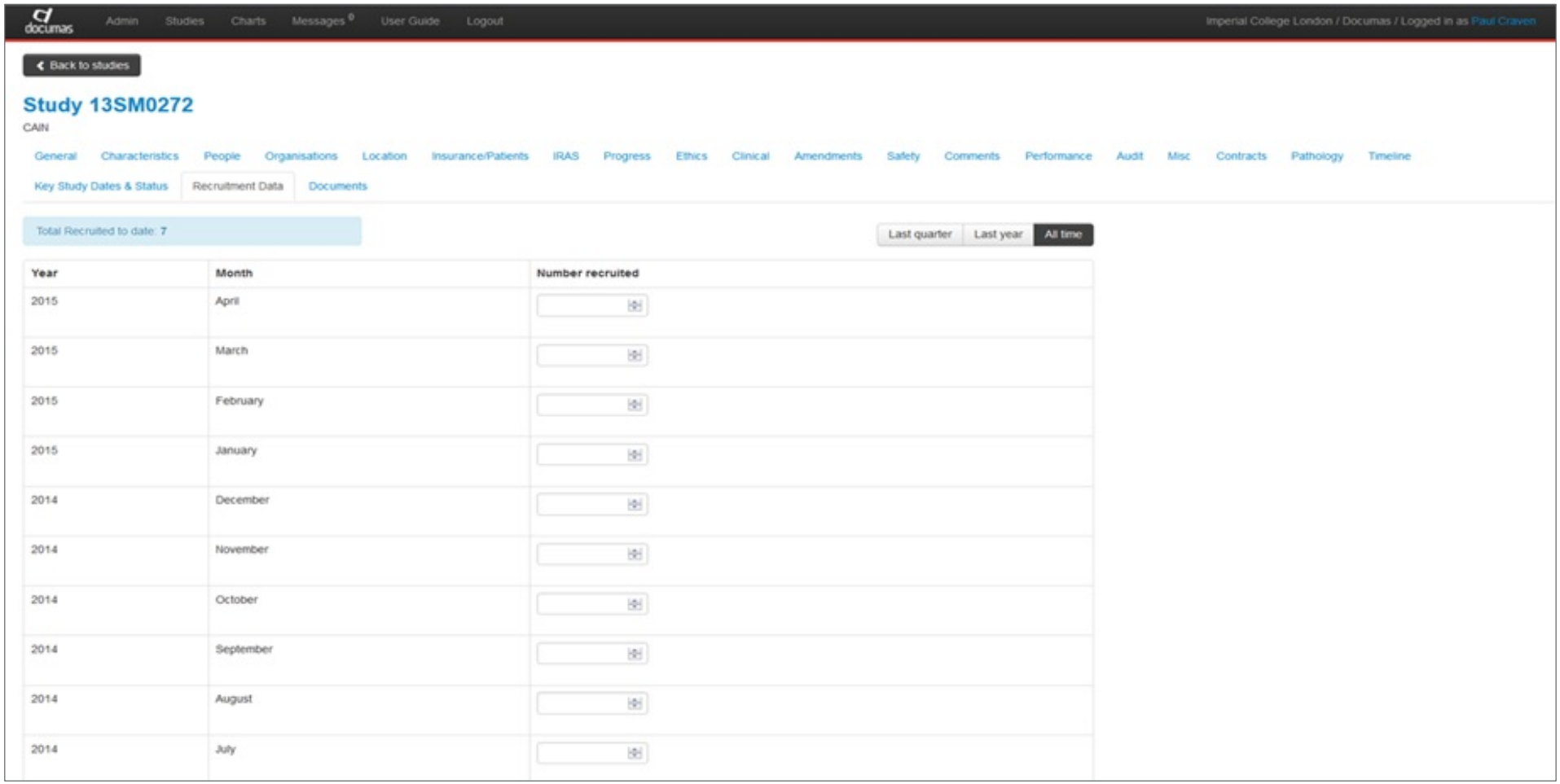
DOCUMAS Clinical Trials Management System



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Joint Working Across NHS and University

- Changed landscape – Health Research Authority / NIHR metrics
- Emphasis now on fast set-up and delivery of patients into trials
- New roles have evolved – Divisional Research Managers / Clinical Research Facilitators
- Responsibilities have devolved from central offices to more ‘local’ clinical settings
  - Study feasibility
  - Liaison with NHS support services
  - Ensuring resources are available
  - Standard contracting and costing