

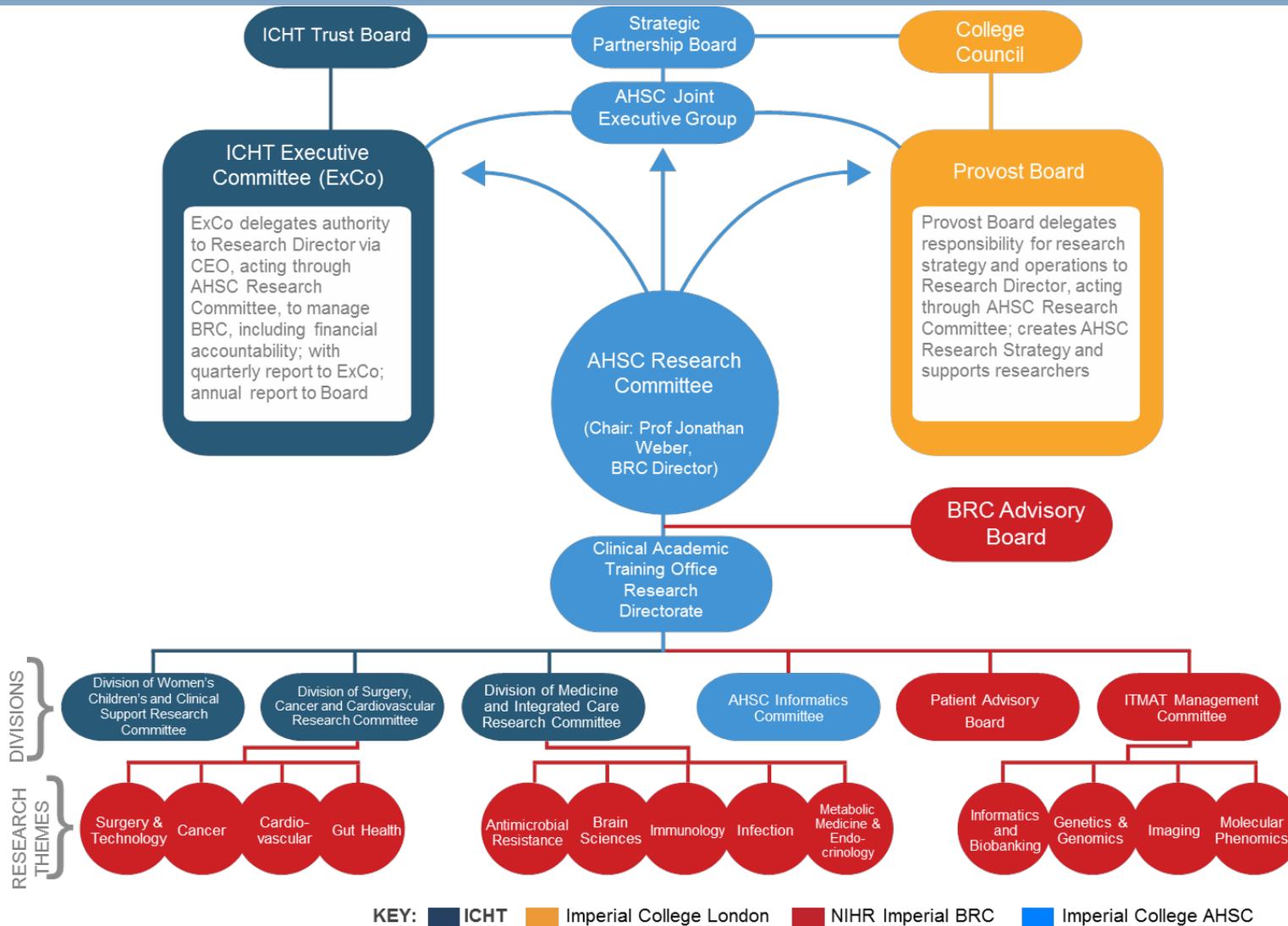
ICHT Divisional Research Management



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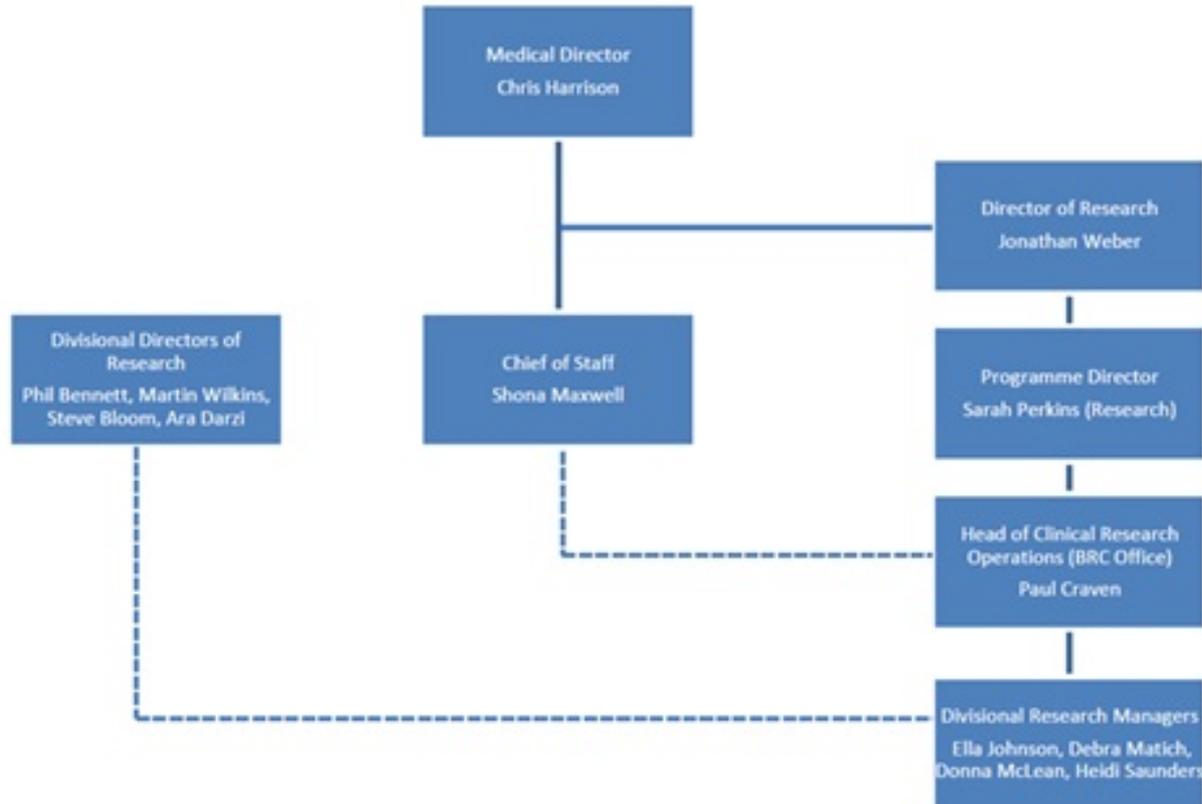
- Dr Paul Craven, Head of Clinical Research Operations

Overall R&D Governance across Imperial AHSC

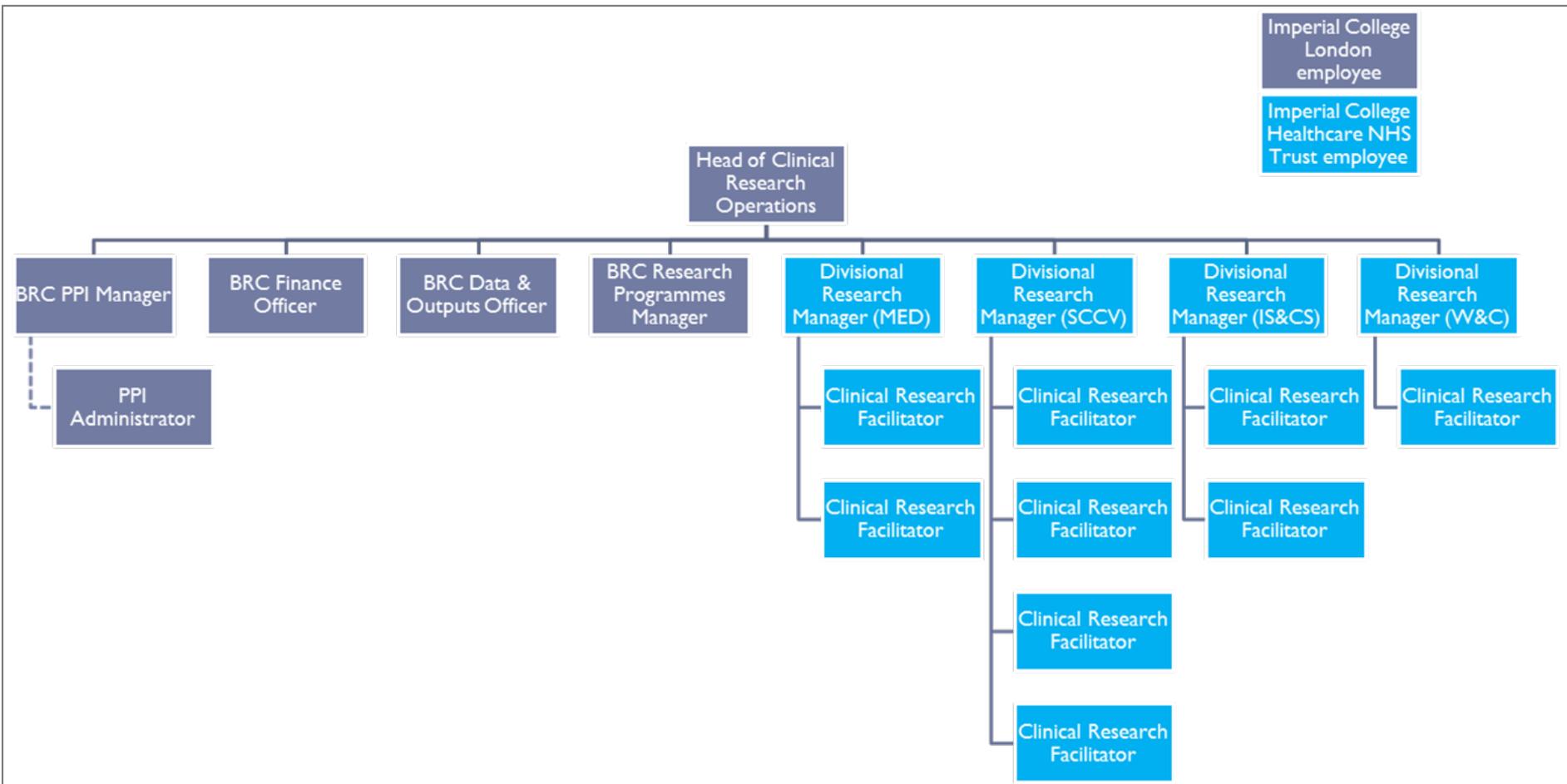


R&D Governance in ICHT

Research



Joint Working Across NHS and University: Clinical Research Operations Office



Divisional Research Management: Study Feasibility



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

NHS R&D Funding Streams

NIHR Imperial BRC: £22.6m per annum

- Experimental medicine (translational of fundamental science into clinic)
- Competitive process; 5 year programme
- 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.

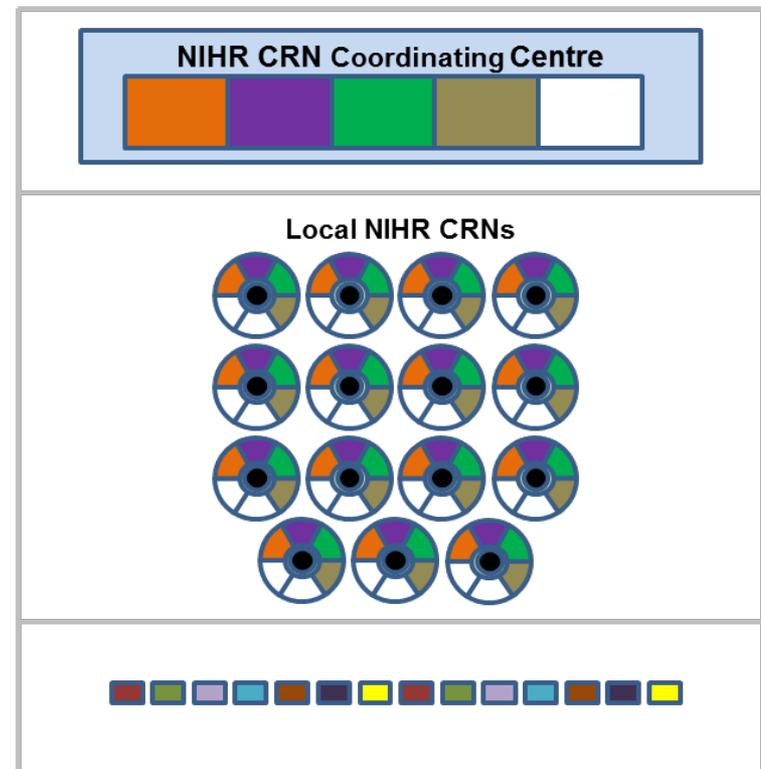
- Contract research
- Legal/management responsibility taken on by sponsor
- Standard contract and costing mechanisms

NWL Clinical Research Network

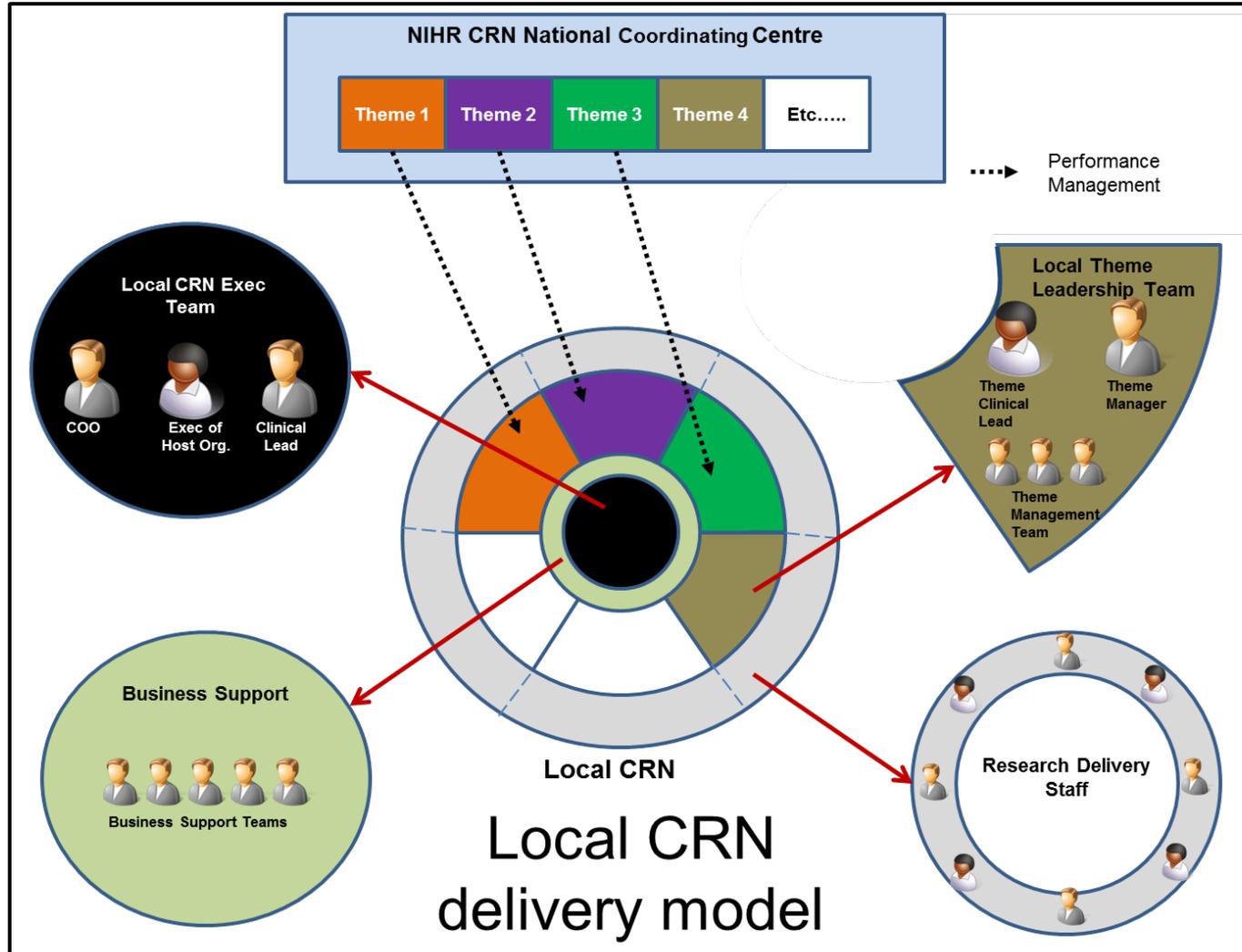
An integrated area-based model

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



NWL Clinical Research Network



NWL CRN: Performance Metrics Dashboard

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



National Institute for
Health Research

Performance Report: CRN: North West London February 2016

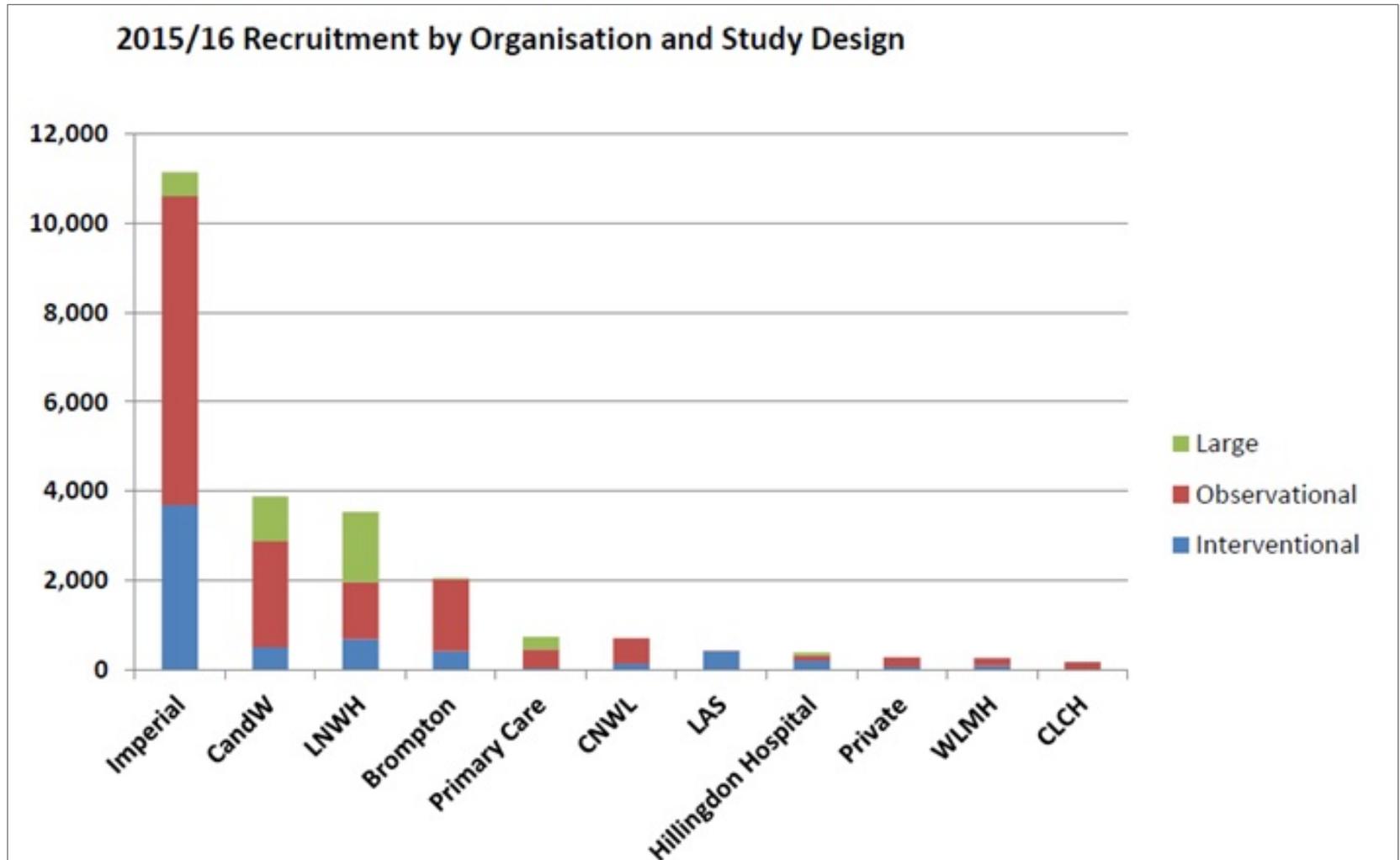
Clinical Research Network

Objectives <small>all objectives relate to NIHR Portfolio studies</small>		North West London Measure	NWL Local Targets		National Measure <small>(see note)</small>	
			Target	Performance	NWL performance	National performance
1	Increase the number of participants recruited	Number of participants recruited in a reporting year	24,168 <small>26,374 FY</small>	102%	92% <small>28,989*</small>	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 <small>150 FY</small>	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 <small>309 FY</small>	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

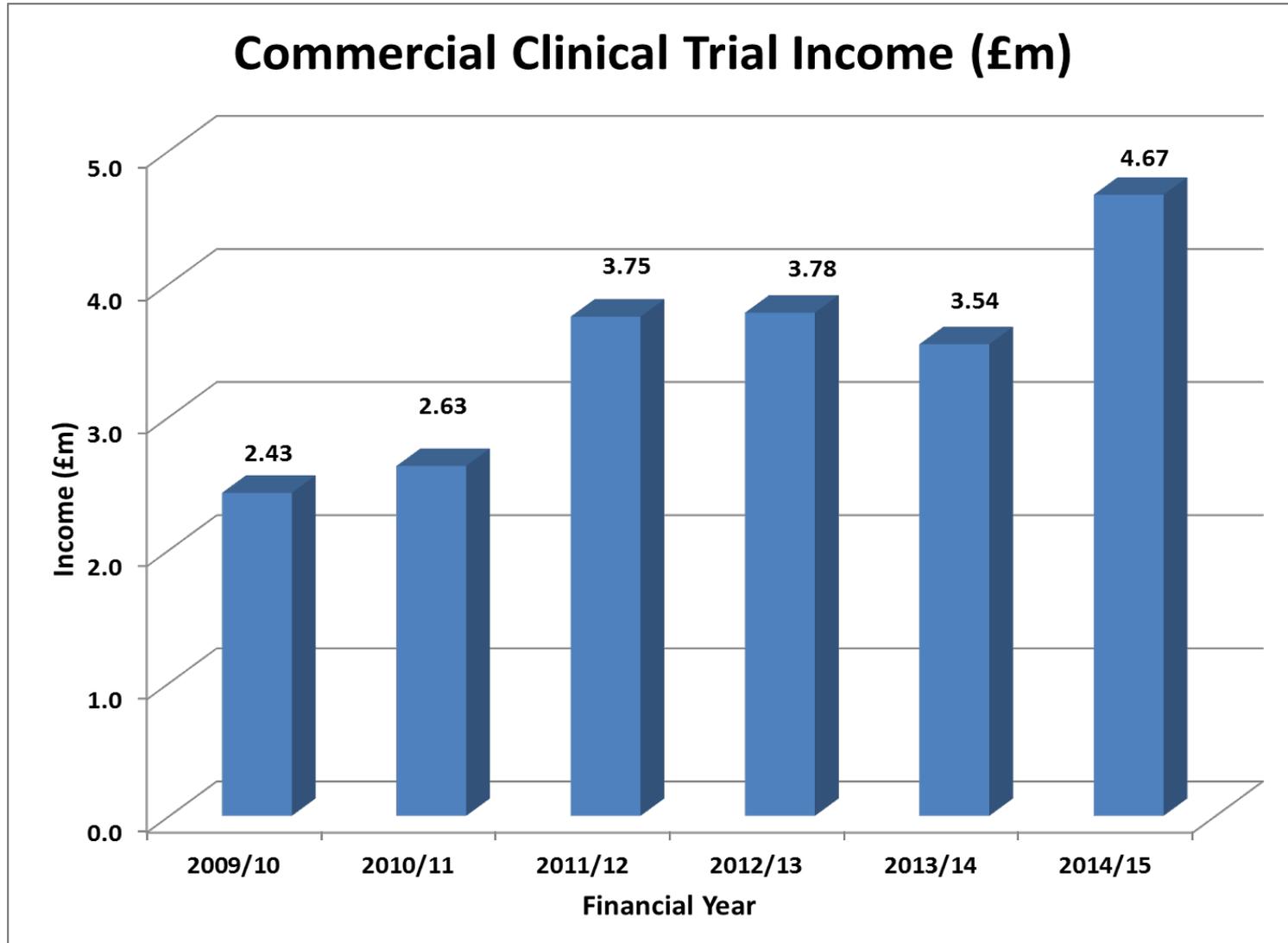
ICHT Performance in NWL CRN



Commercial Contract R&D Studies

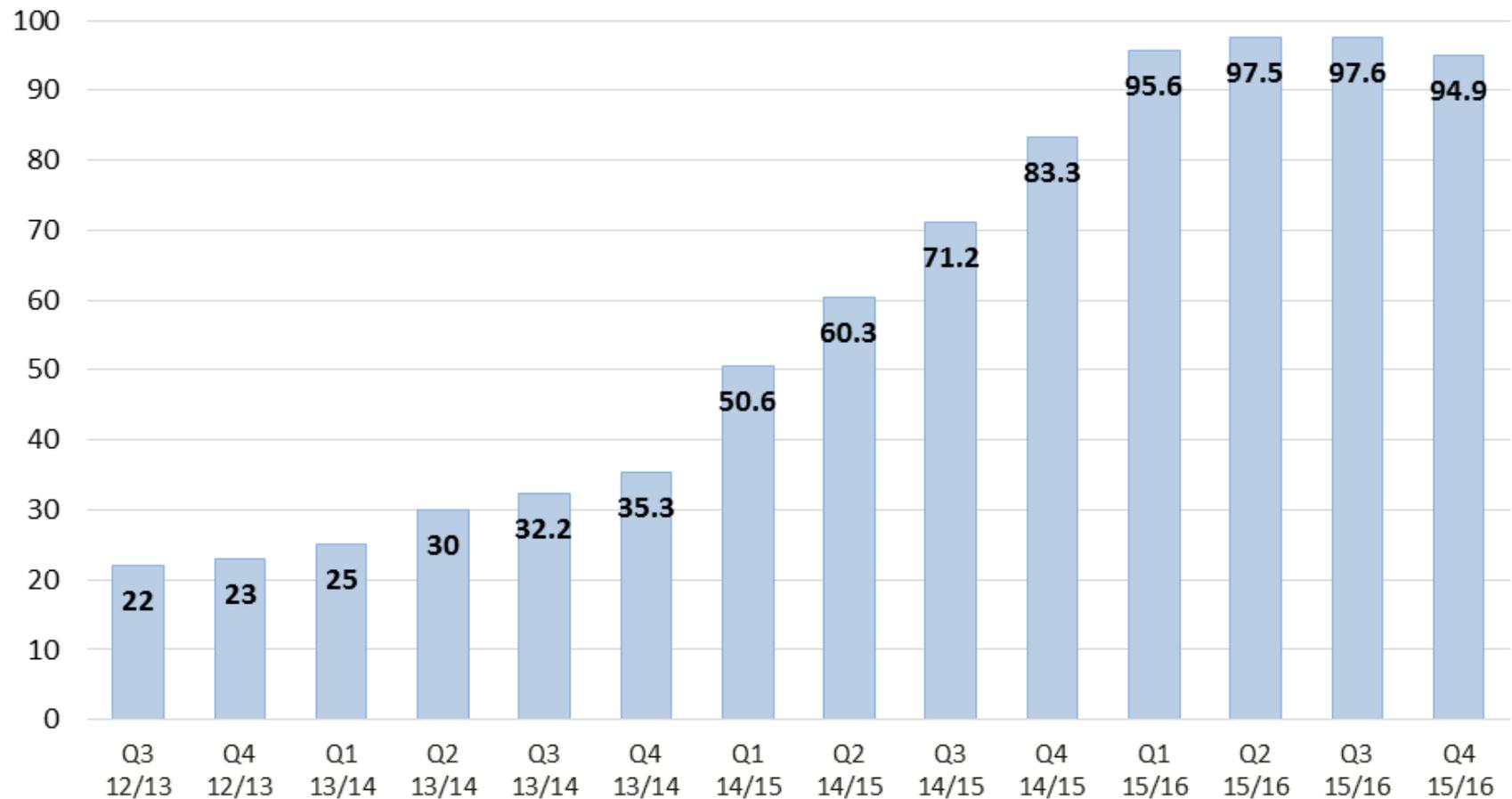
- Pharma / medtech contracts with one or more NHS sites
- Legal responsibility for design and conduct of study lies with external commercial organisations ('sponsorship')
- ICHT acts as a site to recruit participants and carry out study according to protocol ('to time & target')
- Any IP developed is 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

Commercial Trials Income



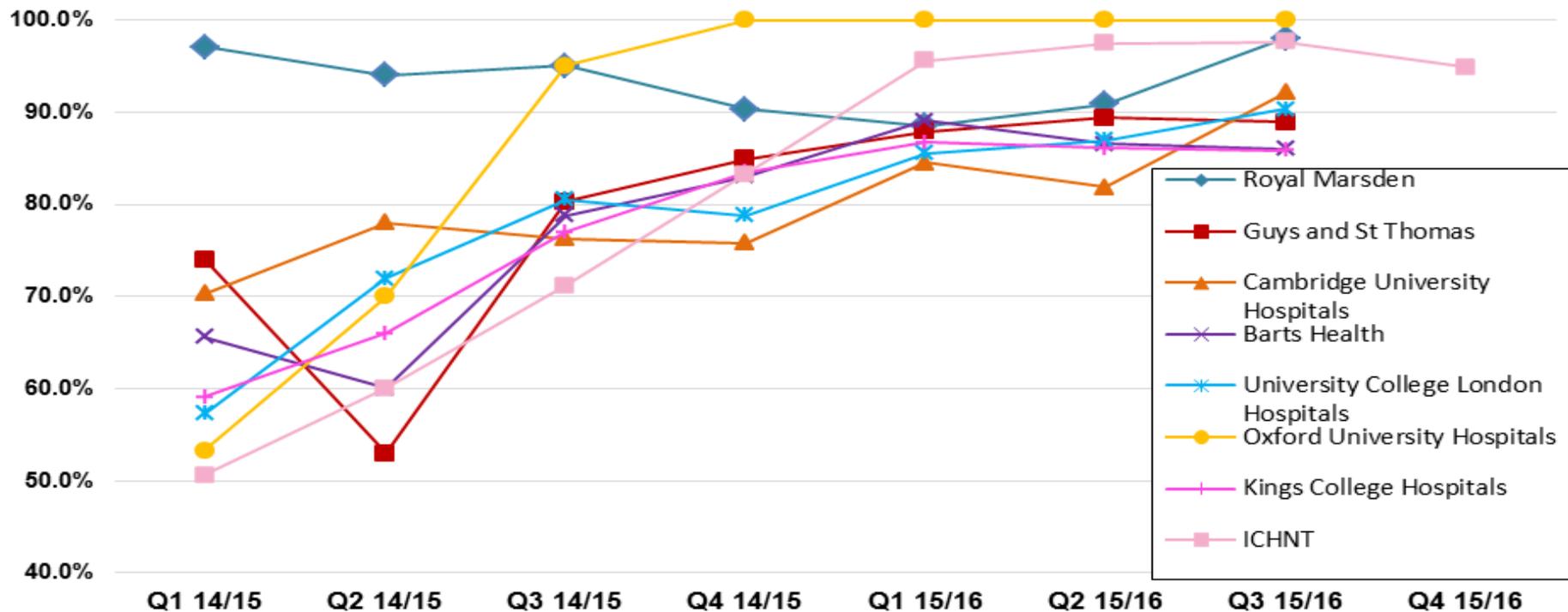
NIHR Performance Metrics: Initiation

Fig.1. % ICHT studies that met 70-day benchmark (adjusted)



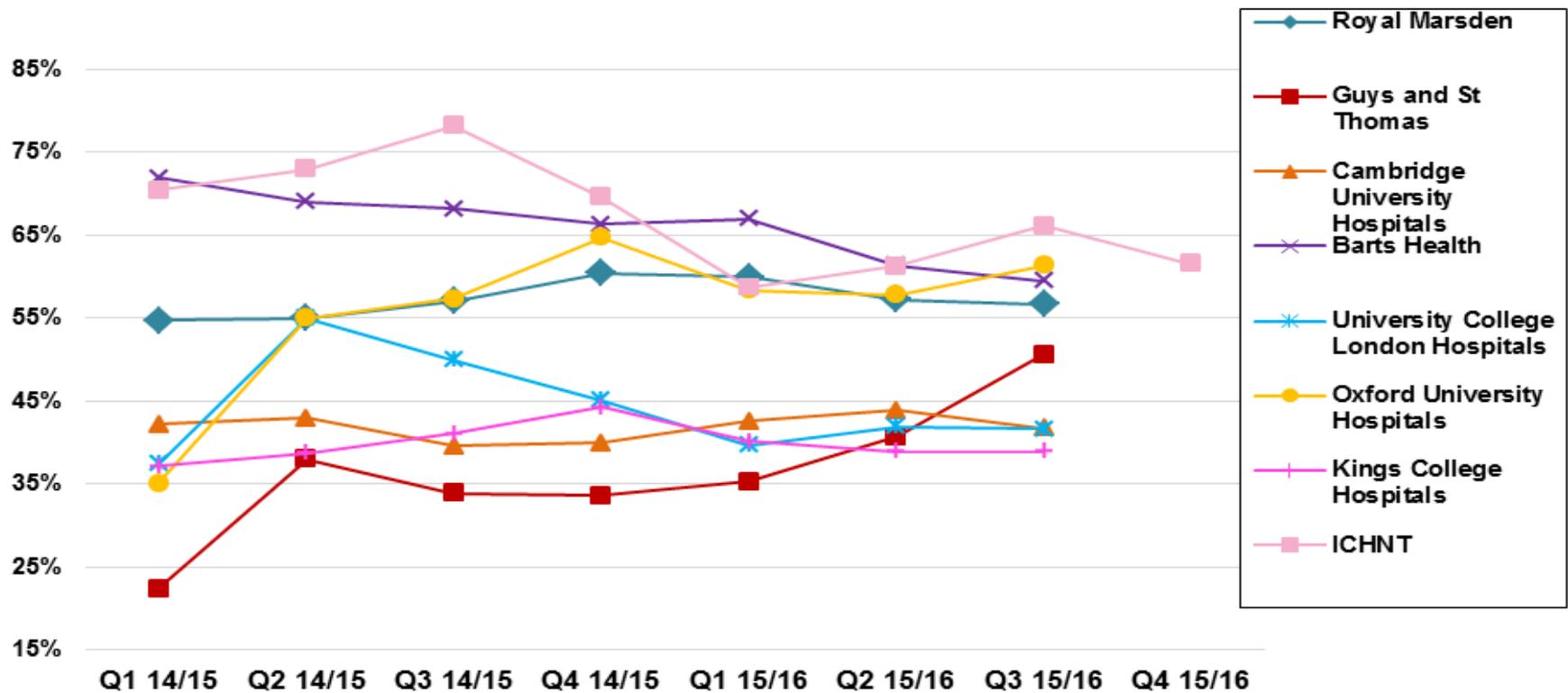
NIHR Performance Metrics: Initiation

Fig.2. Recent Initiation Metric Performanc for ICHNT and Key Comparator NHS Trusts



NIHR Performance Metrics: Delivery

Fig.3. Recent Delivery Metric Performance for ICHNT and Key Comparator NHS Trusts



DOCUMAS Clinical Trials Management System

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Documas reference

Short Title

Long Title

Person

Checkbox

Study status

Rec ref

CSP Number

EudraCT Number

Search Results

5 records found

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Documas Reference	Rec Ref	UKCRN Portfolio ID	Principal Investigator	Long title	Study Status	Study Status (PI)	Valid Submission	R&D / SSA Approval	Date First Patient RECRUITED (NEW FIELD)	Target number of patients	Date agreed to recruit to time & target (planned)	Commercial?	Sponsors	BRC Study Type
15SM3027			Dr Onn Min Kon	An exploratory, randomised, double-blind, placebo-controlled study of the effects of dupilumab on airway inflammation of adults with persistent asthma - Liberty Asthma Expedition study										
15SM2505	15/LO/0444		Dr Onn Min Kon	Nasal, Tracheal and Bronchial Mucosal Lining Fluid	In Recruitment		31/07/2015	31/07/2015					Imperial College Healthcare NHS Trust	

Summary

Note: Please click on a study to begin ✕

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Study 13SM0272

CAN

General Characteristics People Organisations Location Insurance/Patients IRAS Progress Ethics Clinical Amendments Safety Comments Performance Audit Misc Contracts Pathology Timeline

Key Study Dates & Status Recruitment Data Documents

Total Recruited to date: 7 Last quarter Last year All time

Year	Month	Number recruited
2015	April	<input type="text"/>
2015	March	<input type="text"/>
2015	February	<input type="text"/>
2015	January	<input type="text"/>
2014	December	<input type="text"/>
2014	November	<input type="text"/>
2014	October	<input type="text"/>
2014	September	<input type="text"/>
2014	August	<input type="text"/>
2014	July	<input type="text"/>

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