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Research support roadshow 2016

***Hammersmith**: 20 June 2016, 13:00-15:00* *(Wolfson Sem Rm 2)*
***St Mary's**: 21 June 2016, 10:00-12:00* *(G62 Committee Rm)*
***South Kensington**: 23 June 2016, 10:00-12:00* *(Huxley LT140)*

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Welcome and Introduction

William Mortimer

- Director, Joint Research Office

Teams that support and facilitate research operations in the Faculty of Medicine:

- **Joint Research Office**
- **Joint Research Compliance Office**
- **Biomedical Research Centre**
- **Patient & Public Involvement in Research**

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Programme

A. Presentations

1. JRO overview, *William Mortimer, Director JRO*
2. JRO grants:
   a. Pre-award, *Scott Wheatley, Head of Grants*
   b. Post-award, *Tom Grieves, Senior Grants Administrator*
   c. EC, *Nataleen Gould, Grants Manager (EC)*
3. JRO contracts, *Tania Palalic, Head of Contracts*
4. JRCO, *Gary Roper, Head of Regulatory Compliance*
5. PPI, *Markella Boudioni, PPI Manager*
6. BRC, *Paul Craven, Head of Clinical Research Operations*
7. ICHT Divisional Research Management, *Paul Craven*

B. Q&A session

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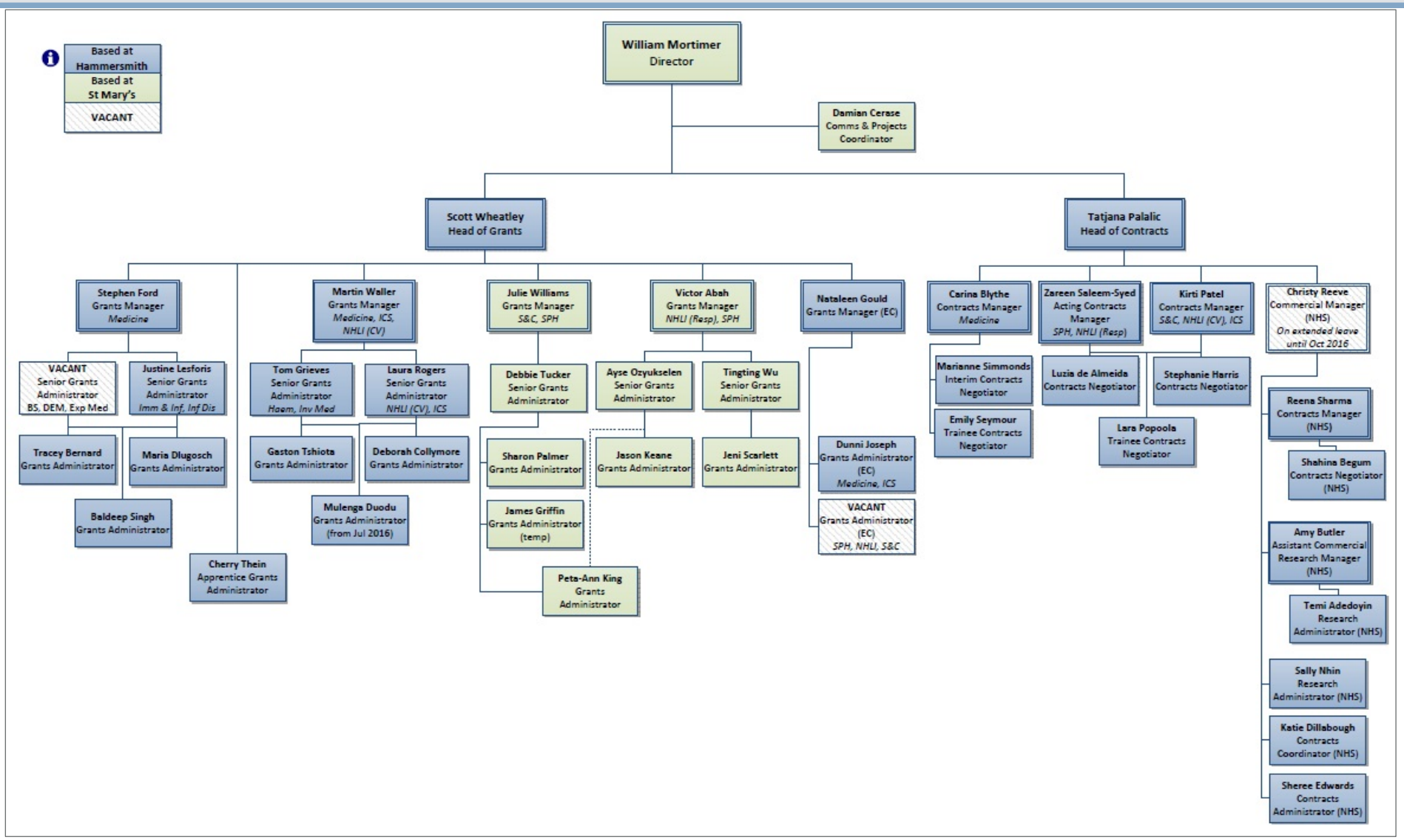
Joint Research Office



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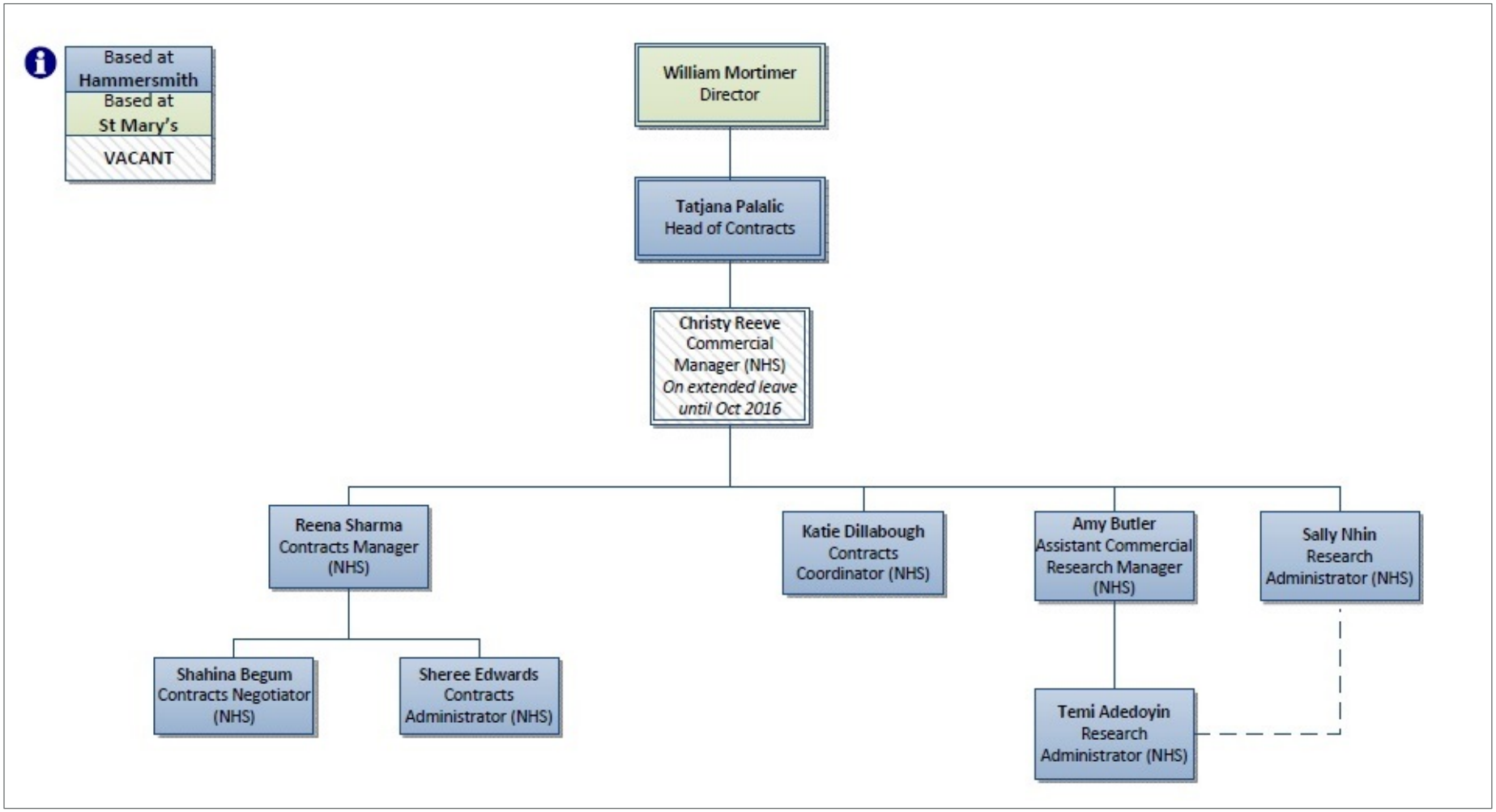
JRO Trust Team



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Joint Research Office: Grants Pre-award

Grants Pre-award

- Scott Wheatley, Head of Grant Administration for Faculty of Medicine

JRO Website - http://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/

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Grants Pre-award

1. 5 day rule – Why we require 5 days submission to the JRO prior to funder deadline.

   New Starter Page on ICL website:

   http://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/resources/newstarters/

2. Online systems: (a) Funder approvals (b) InfoEd approvals

3. Responsibility – if application is submitted late for checking, risks and consequences

4. Checklist – what the JRO does when an app is submitted to research services

5. Returns and rejections of applications due to costs or attachments

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1. Why the JRO requires five days

JRO requires 5 days due to a volume of applications and multitude of checks required for us to submit the best quality applications to funder.

- The research has been costed and priced appropriately and that the recovery (i.e. price as a percentage of cost) is acceptable to all parties
- Time to review terms and conditions of the funder and call guidelines
- Proof of third party responsibility and costs
- NHS costs have to be calculated been approved by the Trust (Sally Nhin – Sally.Nhin@imperial.nhs.uk, or Temi.Adedoyin@imperial.nhs.uk in Sally's absence)
- Ineligible costs are removed from the application
- Allows the JRO and section admin to resource better with receipt of multiple applications (yours isn't the only one!)
- For 14/15, 85% of applications were received within the 5-day window
- Of which, 30% were received on final day of funders deadline

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2. Online Systems: Approvals and InfoEd

- JRO are happy to check costs before submission of the InfoEd and application.
- Various funders have different tiers of approval.
  - Bloodwise – PI submits, approval goes to Co-Is, HoD and finance officer (JRO)
  - JeS & Grants Tracker for Wellcome Trust - More direct, PI approves then JRO.
- Kidney Research UK require governance approval at application stage, so please notify Gary Roper (Head of Regulatory Compliance) and JRO at earliest opportunity. Without approval, we can't submit to funder.
- Some calls under National Institutes of Health Research also require Gary's approval. Please check guidance.
- Sub-projects. If the PI is in another faculty then approval is required by their HoD etc
  - Make sure that any other faculty working with the lead is forewarned and relevant approvals in place.

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3. Responsibility if application is submitted late for checking, risks and consequences

- Any under-costing issues will be the responsibility of the dept/PI if application is submitted late to JRO.
  - Research Partner costs: Important we have copies of the Universities' costs, as any mis-costing will be the responsibility of Imperial College.

- JRO can advise PIs and department of costs that should be included:
  - Advertising, computer charges, overheads, travel

- Maximising cost recovery:
  - Increase senior staff time; IT support charges, facility charges

- Charge Out Facilities. Please use the hourly charge out rate:
  - https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/research-office/internal/Charge-Out-List-Publication.pdf

- Animal costs agreed by CBS Unit (at least 10 working days before the deadline!)

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4. Checklist

Pre-application Checklists are available on the JRO website under Grants:

http://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/grants/fivedayrule/

- InfoEd Proposal Number (P-number) –
- Acronym / Title –
- Start Date and Duration (9 MONTH MINIMUM LEAD TIME – dependent on call) –
- PI name –
- Funder / (Originating Funder) –
- Type of Award / Funding Scheme / Call –
- Project Type (e.g. clinical trial, lab based) –
- Funder Deadline for Submission –

Examples Check:

The correct exchange rate has been used taken from the Exchange Rate Table

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5. Return and rejection of applications due to costs or attachments

- Applications returned. Time and effort to re-do and re-submit. College reputation.
  - Publication/CV (separate documents), Letter of Support, Font Size.

- NERC - College should adhere to the regulations set out in the NERC handbook e.g. attachments should be of the correct length. Proposals not adhering to the rules will be automatically rejected and will not be returned to applicants for corrections.

- EPSRC - Recently introduced rule that they will not return any errors and they will continue through to peer review in their current form.

- MRC may follow suit.

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Further guidance

Further information can be found at:
http://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/

- Making background checks – no ethical objections / credit worthiness
- How to develop, cost and submit an application
- Award Notification - What to do and which JRO team will support you
- Managing Projects and Golden Rules (both pre & post award)
- Project reconciliation and closure

Research Office - http://www.imperial.ac.uk/research-and-innovation/research-office/

Lastly, the JRO will do their best to provide a first class service to you during the pre-award stage. The more time we get, the more we can work with you in submitting the best quality application to the funder.

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Joint Research Office: Grants Post-award

Post-award

- Tom Grieves, Senior Grants Administrator

JRO Website - http://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/

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Grants Post-award

The post award project lifecycle:

- Receiving an award;
- Initial set-up procedures;
- Award initiation;
- Managing active awards;
- Closing accounts

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Grants Post-award: Receiving an Award

Awards will normally be received by funders to various stakeholders:

- RCUK – PI and JRO will receive notification via Je-S:
  - PI will be notified of successful application
  - Official Award Offer Document will follow
- Grants that require JRO signatory at application stage, usually received by JRO or Research Office (most charities, funders that use online systems with JRO as signatory).
- Other funders where PI is primary contact (e.g. industry) usually received by PI.

Please inform JRO as soon as you receive an award letter!

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Grants Post-award: Receiving an Award

Awards involving humans, their tissue and/or data require ethical approvals before an award will be activated on ICIS.

- Please forward details of ethics with the award letter if possible.
- If ethics will be applied for during an award, budget items dependent on ethics will be uplifted once approval has been granted.
- JRCO will give final confirmation.

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Grants Post-award: Initial Set-up Procedures

Depending on the T&Cs of the funding, there may be additional steps required before we can set-up an award:

- Standard T&Cs – JRO can proceed with set-up e.g. RCUK.
- T&Cs from regular funders – likely to have been approved previously and JRO can sign-off:
  - Where T&Cs have been updated – review by contracts required.
- T&Cs from new funders – require review by Contracts and relationship review.
- T&Cs/contracts from industry – require negotiation by Contracts.
- Research Collaboration Agreements where Imperial is a 3rd party or for 3rd parties where Imperial is lead – will require negotiation by Contracts.

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Grants Post-award: Award Initiation

Once T&Cs/contract reviewed and approved, JRO, Contracts or PI will be responsible for approving and accepting grant awards.

Once Award has been accepted, we can continue with set-up:

- There must be a valid InfoEd submitted and approved, which matches the award value – will have been completed at pre-award, if not approved this will delay set-up.
- If award value differs from InfoEd, JRO will liaise with dept. to understand why – giving sufficient time at pre-award will reduce this issue.
- JRO will review award documentation and set-up the grant in line with agreed obligations – we aim to complete this in five working days from approval. Main inhibitors to this are ethics and InfoEd approvals.
- JRO will produce a Budget Form which will detail the budget available to spend on this account, along with other key information, e.g. milestones, reporting deadlines.

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Grants Post-award: Award Initiation

- JRO will send award set-up email including award letter/contract, budget form, golden rules to key stakeholders – please read this!

- JRO will notify contracts of any sub-agreements required.

Useful resources:

Research Office Website – Managing Projects

JRO Website – Grants Processes Page

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Grants Post-award: Managing Active Awards

Budget Management

- Awards are made on an FEC or non-FEC basis as indicated at pre-award and on the budget form. FEC awards require a contribution from the College.
- For all awards, the 100% budget is set-up on ICIS and is available to the PI to spend.
- Please try to maximise budgets – This increases research volume for the College which positively affects the REF return and potentially additional funding streams e.g. B/C-stream.
- Please spend in line with the budget as set up on ICIS – Ineligible costs must be met by the department. RO Guidance on ineligible costs.
- If the scope of the work has changed please refer to JRO for guidance on budget amendments.

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Grants Post-award: Managing Active Awards

JRO

- Claims list management, i.e. invoicing, interim and final reporting (GA).
- Costing and approving HR forms submitted by department (SGA).
- Account reviews for major funders, e.g. RCUK, WT, CRUK (SGA).

Department

- Scientific reporting.
- Timely submission of HR forms – please submit well in advance of payroll deadline to reduce need for HR18s and more work for JRO and dept.
- Completion of timesheets for split funded staff on RCUK/NIH. JRO Guidance.
- Ensure all costs are posted in a timely manner.
- Chase supplier invoices for valid commitments/close commitments no longer needed – commitments will not be included in financial reports if not backed up with invoice/receipt.

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Grants Post-award: Closing Accounts

When all reports and/or claims have been submitted and paid, the account will be in surplus, in deficit or balanced.

Surplus

- If award is fixed price surplus is kept by PI/department.
- Otherwise refund is due to funder.

Deficit

- Costs charged after end date (e.g. commitments not realised before final report).
- Funder declines to meet all costs.
- Department to remove costs via a journal.

When income equals expenditure the JRO will close the award on ICIS.

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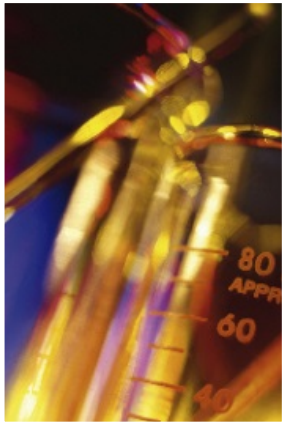
Joint Research Office: EC Team



EC

- Nataleen Gould, Grants Manager (EC)

JRO Website - http://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/

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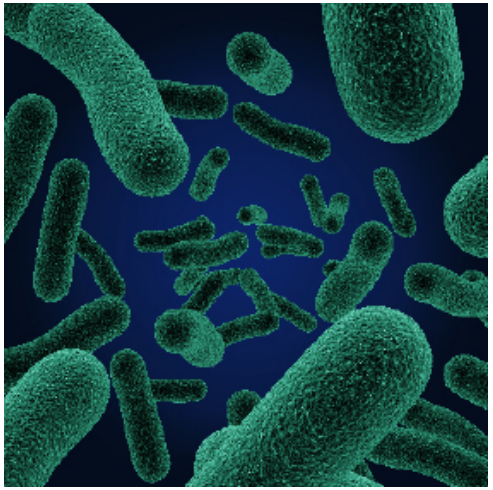
European Commission

Pre-award

- First steps
- Application checklist
- Imperial as coordinator
- Portal
- Preparation stage



Post-award

- FP7/H2020
- Timesheets
- Payments

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First steps

1. Call details (Sent to JRO by PI/Department - ERC, MSCA, other research and innovation actions)
2. H2020 calculator – Excel spreadsheet GBP/Euros (ERC – European Research Council, MSCA - Marie Sklodowska-Curie, R&I (Research & Innovation Action)
3. INFOED (5-day-rule applies - for the benefit of the academic)

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EC application checklist

1. Exchange rate (finance calculator) - link
2. Equipment (College's tendering process is adhered to) - link
3. Sub-contracts (article 13 of the MGA) – tendering process and best value for money
4. Trust costs - (approved by Sally Nhin and attached to INFOED-classified as article 11 of the MGA)
5. Audit costs included – threshold €325k direct costs (£4000 + inflation excl VAT for R&I projects and £9000 for ERC projects)

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Imperial as coordinator

Project Management Considerations

1. PMO (Programme Management Office)
2. Project manager
3. Outsourcing

Department approval is required when taking on the role of coordinator (as early as possible).

http://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/grants/euprojects/ - Project management considerations and H2020 notes for Imperial's researchers.

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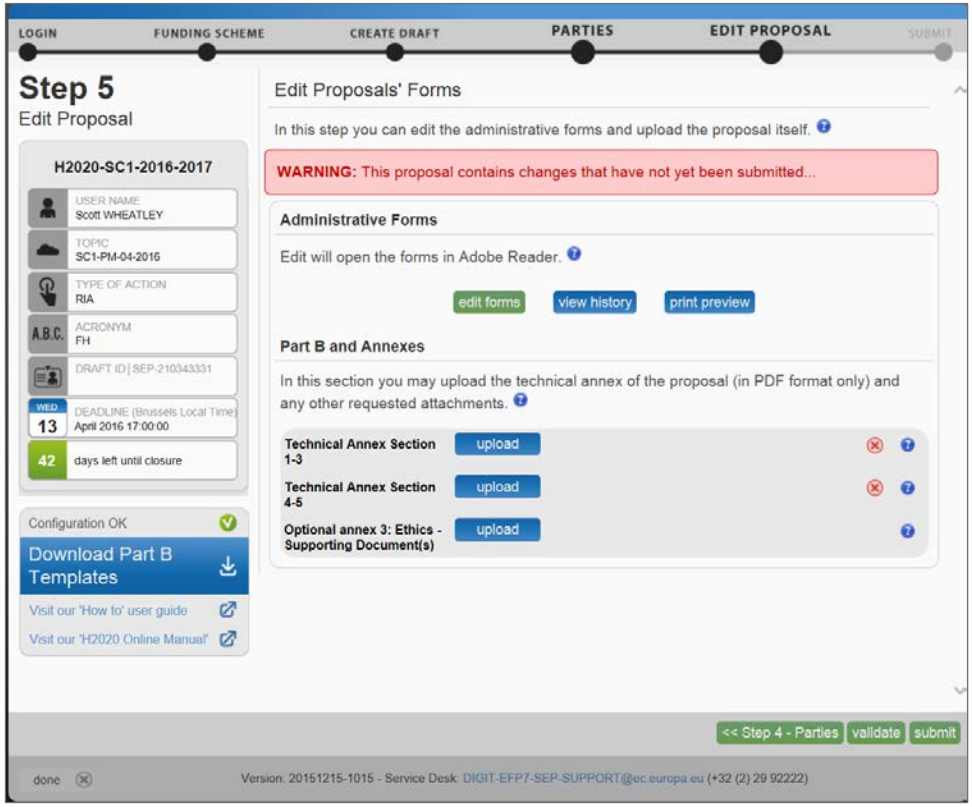
ECAS (EC portal)

1. PI/coordinator grants JRO (Scott Wheatley) as a contact for the project
2. JRO checks budget on proposal matches approved costs on InfoEd
3. PI/coordinator submits proposal (please do inform JRO if changes are made prior to submission)
4. Figures on H2020 budget sheet, InfoEd recovery, ECAS proposal figures should all match



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Preparation stage (previously known as negotiation stage)

1. Application is successful – coordinator/PI is invited by the EC to prepare contractual documents
2. JRO checks budget on EC portal to ensure it matches our approved internal budget
3. JRO confirms to the legal team that the DOH (declaration of honour) and grant agreement can be signed

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EC – Post-award (FP7 & H2020)

1. Project set up on ICIS (activation email sent to all parties)
2. JRO responsible for submitting Imperial's financial statements (Form C submission to the EC for FP7 and H2020)
3. Audits – certificate on financial statements. JRO responsible for submitting expenditure report and timesheets to auditors. External auditor is PKF Littlejohn.
   (FP7 - €375K Euros AUDIT THRESHOLD / H2020 - €325K Euros AUDIT THRESHOLD)

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Timesheets

All staff charged to FP7 and H2020 projects to submit timesheets.

Timesheets submission – EMAIL: eujrotsheets@imperial.ac.uk (JRO checks timesheets submitted – hard copies to be retained in department)

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EC payments

1. Pre-financing - % calculated by EC
2. Interim payments (after each reporting period up to maximum of 85% of the budget)
3. Final payment - 10% (upon approval of final reports)
4. Guarantee fund - 5%

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EC Team: Further Information

Further information

EU Projects and EU JRO team can be found at:

http://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/grants/euprojects/

Research Office European team at:

http://www.imperial.ac.uk/research-and-innovation/research-office/funder-information/european-commission/

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Joint Research Office: Contracts

Contracts

- Tania Palalic, Head of Contracts

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Contracts – Proposal Development Policies

College Policies

- Investigator Eligibility (applicable if there is no funder policy)
- Costing and Pricing (applicable to all external funding)
- Preferred Terms and Conditions (applicable to commercial and non-commercial agreements)
- Approval and Authorisation (applicable to all proposals for external funding)

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Contracts – Preferred Terms and Conditions

Aims

- To provide a College framework for the agreement of terms and conditions in research and research related agreements
- To protect the interests of the College and Investigators
- To set out the preferred contractual position for the core elements of a research agreement, whilst retaining flexibility to take account of the context

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Contracts – Preferred Terms and Conditions

Key contractual principles

- To protect academic freedom to operate in future research projects
- To be able to disseminate research outcomes
- To maximise opportunities in relation to research outcomes
- To minimise financial and reputational risks and the liability of the College
- To ensure activity is capable of being classified as Research – understood as *original investigation undertaken in order to gain knowledge and understanding for the public benefit*

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Contracts – Preferred Terms and Conditions

Core Terms and Conditions

- Payment Terms
- Price
- Publication
- Confidentiality
- Intellectual Property – Background IP, Foreground IP, Commercial License
- Liability and Insurance
- Termination
- Law and Jurisdiction
- Warranties

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Contracts – Preferred Terms and Conditions

Information required for contract negotiations

- Project description – clinical, non-clinical
- College's role in the project – lead, collaborator
- Personnel – employees, students, contractors
- Funding details – commercial, non-commercial, no funding
- Third Party support for the project – cash or in-kind contribution
- Third party involvement in undertaking the project – collaborators, subcontractors, consultants
- Location of the performance of the project – College, Trust, other UK and overseas locations

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Contracts – Preferred Terms and Conditions

Provisions that take most time to finalise

- Financial reporting, invoicing and auditing
- Intellectual Property
- Publication rights
- Warranties
- Adherence to funder's specific policies
- Governing laws and regulations

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Contracts – Preferred Terms and Conditions

Examples of complex contracts

- Multi-centre clinical trials
- Co-funded or co-supported projects – e.g. project funded by a charity with in-kind contribution(s) from a commercial party, and which involves collaborators and subcontractors

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Joint Research Compliance Office (JRCO)

JRCO

- Gary Roper, Head of Regulatory Compliance

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Overview

- JRCO Remit
- Interactions
- Example Approval Process
- HRA Developments

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JRCO Remit

The Joint Research Compliance Office exists to help the AHSC and its researchers meet the requirements of research governance, ensuring Imperial fulfils the legal, ethical and scientific obligations of the healthcare research process.

This is accomplished by using a variety of Standard Operating Procedures that relate to multiple aspects of research management and approval requirements. These can be accessed at:

http://www.imperial.ac.uk/joint-research-compliance-office/standard-operating-procedures/

The JRCO has a dedicated team overseeing research activity across the AHSC. Contacts can be accessed at:

http://www.imperial.ac.uk/joint-research-compliance-office/about-us/staff-list/

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JRCO Interactions

- JRO
- BRC
- CRF
- Support Services
- ICTU
- Tissue Bank
- ICREC

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Example Approval Process for AHSC Sponsored Research

First Contact

- Researcher submits study documents to JRCO for sponsor assessment
- JRCO checks for valid document set and commences sponsor review

Dissemination

- JRCO emails out study documents to PI, Divisions, Contracts and support services as required once initial review completed
- JRCO completes sponsor review and instructs researcher to submit for ethics/regulatory approval

Review

- Divisions complete feasibility review with support services
- Divisions return statement of activities or confirmation of feasibility approval to JRCO. Contracts confirm sign-off (if required)

Confirm

- JRCO conducts final checks and receives HRA approval confirmation
- JRCO confirms readiness to sponsor, PI, Divisions, Contracts and support services

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HRA Approval

The HRA has rolled out an approval process to consolidate ethics and approval requirements for health related research in England.

This requirement covers all health related research being submitted to the National Research Ethics Service (NRES) for review and approval

It also includes all pre existing studies where amendments are being submitted for approval.

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Process

The HRA review process is for research studies taking place in England in the NHS, and approval will be issued on behalf of the NHS. This will provide assurance to the sites, researchers, patients and sponsors that:

- the study has a favourable ethical opinion AND
- the study protocol and arrangements are compliant with relevant legal and regulatory requirements AND
- the study documents are compliant with nationally agreed standards

This is a major change to the approvals process, without the perceived ‘extra’ NHS review process that researchers and companies have struggled with. So research in England will benefit from a streamlined approvals process as well as the unique opportunities provided by the NHS.

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Process

- Single application via (IRAS) for ethics approval in parallel to HRA approval
- Medical Radiation Exposure statements to be collected prior to submission
- Single technical Pharmacy review
- Model contracts or statement of activities to be used
- Research Passport – who needs what type of access – HRA will advise
- HRA approval will be an assurance of regulatory and ethics requirements
- NHS sites will focus on capacity and capability to support the research and ensure local SOPs can meet the needs of the research protocol

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Sponsor Requirements

All non-commercially sponsored applications must be accompanied by a completed Statement of Activities, which details the activities to be undertaken locally and whether these will be undertaken by local or central study staff.

For studies where activities will differ at different host organisations (i.e. where there is more than one ‘site type’ in the study) one Statement of Activities must be provided per site type

HRA assessment will review the consistency of activities described in the Statement of Activities with the description within the protocol, participant information sheet, and other study documents

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Statement of Activities

Includes:

- Study information
- Local site requirements an information
- Schedule of events defined by protocol
- Finance details – site specific
- Material Transfer considerations and process
- List of activities to be carried out at site

This document is evolving in practice and is subject to change following feedback

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Top Level Process for Site Approval

ASSESSING	ARRANGING	CONFIRMING
Assessment of the capacity and capability of the participating organisation to deliver the study. **Endpoint: Joint decision by the Sponsor and Participating Organisation that the Organisations is selected to take part in the study AND listed on the IRAS form.**	Sponsor and participating organisation actively puts in place all the practical arrangements to ensure it has the capacity and capability to deliver the study. A study delivery timetable is agreed. Endpoint: All arrangements are in place. Sponsor confirms site participation. The contents of the Statement of Activities or agreement is ready to be executed and HRA approval has been granted	Participating organisation confirms that it has the capacity and capability to deliver the study by email or execution of the agreement where one is required. Endpoint: Participating organisation is ready to recruit to the study to the timetable agreed with the Sponsor.
Supporting HRA Research Support Functions – Study Specific: **1. Providing internal and external investigators wishing to undertake a specific study at the site with:** **i. Practical support around agreeing arrangements for study set-up.** **ii. Advice on study set-up and legislative requirements.** **2. Providing advice and support on research related to higher degrees to both students and supervisors.** **4. Undertaking an early assessment of operational requirements for the conduct of the study and ensuring there are proportionate systems in place to mitigate and manage any identified study risks, in order to effectively deliver the study through its life cycle.** **5. Ensuring that the NHS organisation has both the capacity and capability to undertake the study – that is, bearing in mind the inclusion and exclusion criteria and the resources required, will it be possible to recruit the required number of participants within the timescale of the study delivery period and conduct the study in accordance with the protocol? This can include discussions with the local study team, NIHR Clinical Research Network (if a portfolio study) and sponsor leading to a proposed start date.** **……** **NOTE, where CRN feasibility services are used prior to the assess stage, this aligns with:** **3. Supporting investigators to prepare and submit expressions of interest to commercial and where required non-commercial sponsors.**	Supporting HRA Research Support Functions – Study Specific: 6. Supporting investigators in putting in place the necessary practical arrangements to conduct the study protocol in line with the responsibilities agreed with the sponsor, including all required safety arrangements. 7. Ensuring that the appropriate management/supervision and oversight arrangements are in place for all aspects of the study. 9. Ensuring that the ethically approved arrangements are in place for identifying and approaching potential participants, including managing any transfers or referrals of patients. 12. Having delegated responsibility for, or working with, their Human Resources Department to operate the Research Passport Scheme to issue (in line with HRA Approval conditions) Honorary Research Contracts and Letters of Access for research staff not employed by that NHS organisation.	Supporting HRA Research Support Functions – Study Specific: 8. Executing contracts/agreements and agreeing a budget for the delivery of the study in line with HRA Approval conditions. 13. On the basis of HRA Approval, confirming that the site will participate and finalising with the sponsor a timetable for study start/study initiation and study delivery. …… NOTE, organisations are expected to supportively manage studies throughout their life cycle through-out the stages: 10. Managing the resources required to deliver the study both at study set up and throughout the study life cycle in line with HRA Approval conditions, HSG(97)32 and AcoRD guidance. 11. Ensuring the site recruits the number of participants stated in the original application (or a revised target) within the time line agreed with the sponsor. 14. Following an updated HRA Approval make the necessary arrangements to implement amendments or, very occasionally and in discussion with the sponsor, withdraw from participation in the study if the amendment adversely affects the capacity and capability of the organisation to deliver the research to the new information.

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Site Approval

- Consists of capacity and capability assessment
- Local SOP compliance checks
- No regulatory checks as these reside with sponsor and HRA
- Statement of activities or contract
- Organisational confirmation – via email to sponsor
- Confirmation can only occur once HRA approval is in place
- Sponsor responsible for communicating with sites

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Summary

HRA approval will evolve over the next year

Ethics approval will form part of HRA approval with a single application route

Governance and approvals processes are very involved and take time so plan well ahead

Make sure you engage early with approvers and support services so your research is not delayed.

Any Questions?

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Patient and Public Involvement (PPI) and Public Engagement (PE) in Research

NIHR Imperial Biomedical Research Centre (BRC) and Patient Experience Research Centre (PERC)

- Dr Markella Boudioni, Patient and Public Involvement Manager

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Overview of presentation

- Definitions and strategy:
  - Patient and Public Involvement (PPI)
  - Public Engagement (PE)
  - Participation
- Research funding bodies PPI/PE requirements
  - NIHR
  - Other
- PPI in research – Benefits
- Advice, information and support for PPI

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Definitions (NIHR BRC requisites)

Patient & Public Involvement (PPI)

- *Patients and the public being actively involved in the activities, organisation and governance of specific research projects or research in general.*

Public Engagement (PE)

- *Providing and disseminating information and knowledge about research to the public; discussing, consulting the public.*

Not to be confused with Participation in Research *(as subjects/research participants)*

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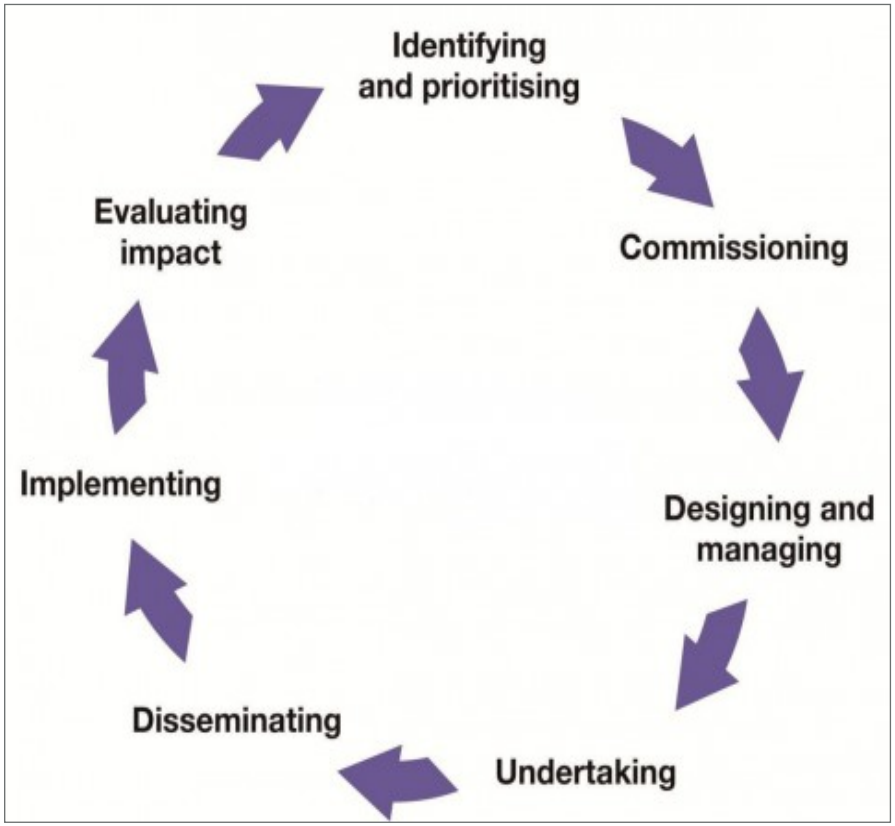
PPI/PE Strategy (2014-2017)

Overall aims

- Embed patient and public involvement (PPI) across the whole organisation with active consultation and collaboration in research projects, research themes and board level, and where feasible user-led projects
- Active public engagement (PE) with a proactive approach to make our work accountable, transparent and relevant to the public



The research cycle
(INVOLVE Briefing note eight: Ways that people can be involved in the research cycle)

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PPI/PE Achievements

1. Building capacity and expertise
   - BRC PP panel
   - Rewards and recognition guidance
   - PPI Grants
2. Monitoring and learning
   - Training/resources for researchers, patients, public
   - Monitoring of activities, sharing good examples
3. Collaborating
   - Imperial BRC PPI/PE Virtual Network
   - Imperial & Partners PPI Research Forum
   - BRC PPI Network
   - 100,000 Genomes PPI Network
4. Assessing the impact of PPI/PE
   - 100,000 Genomes Project National Service Evaluation
   - Number of projects / teams / themes
   - Level of involvement / engagement
   - PP co-design & co-production of BRC Open Day
   - PP co-reviewing Grants

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PPI/PE Requirements – NIHR Funding

- The NIHR
  - expects the active involvement of patients and the public
  - recognises that the nature and extent of active PPI is likely to vary depending on the context of each study award
  - expects full proposals to demonstrate **substantial, convincing engagement with patients and the public** at every stage of the research project, from early design through to publication

- Planning public involvement
- Ongoing public involvement

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PPI/PE requirements – NIHR funding

Planning public involvement

- Were patients and the public actively involved in **identifying the research topic or prioritising the research questions**?
- Were patients and the public actively involved in **preparing the application**?

- **If YES to either or both** questions, give details. Describe:
  - **how** PPI has informed and/or influenced the development of the application
  - **how** patients and the public have been involved
  - provide names of individuals and/or groups,
  - outline the **activities** they have been involved in and
  - how this involvement has or has not, **influenced or changed this research application**.

- **If NO to either or both** questions please explain **why** patient and public involvement was not necessary

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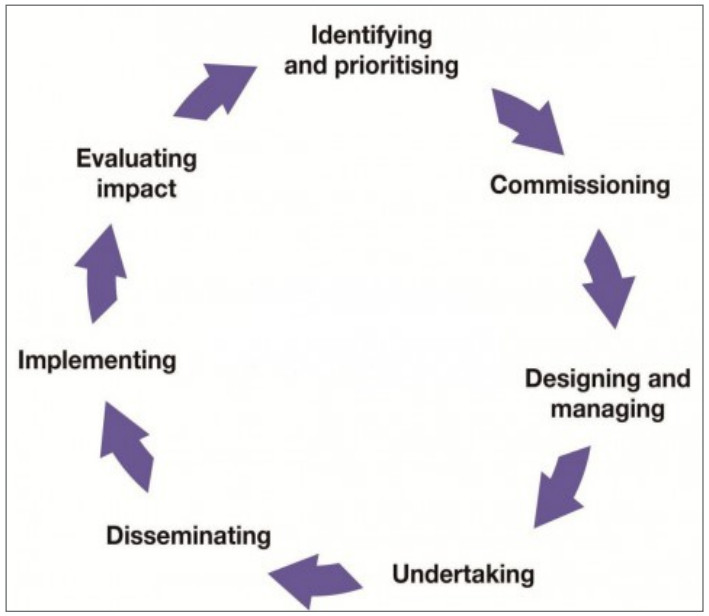
PPI/PE Requirements – NIHR Funding

Ongoing public involvement

- Please indicate **the ways in which patients and the public will be actively involved** in the proposed research.
- If active involvement is planned, please give more details, including:
  - **how** it will benefit the research,
  - **the reasons (why)** for this approach and
  - arrangements for **training and support**
- Describe the **way** the public will be involved
- Provide names of individuals and/or groups
- Outline the **activities** they will be involved in
- Explain **how** it will **benefit** the research.

The research cycle



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PPI/PE Requirements – MRC

- **MRC Clinical Trials Unit**
  - Guidance for cancer trial managers about PPI
  - Guidance about PPI in clinical trials
  - Guidance about PPI in systematic reviews
  - Policy about PPI in systematic reviews

- **MRC Guidance for applicants**
  - Public Engagement in Research
  - Pathways to Impact

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PPI in Research: Benefits

- Democratic Principles
- Health and social care policy commitment and initiatives
- Research Quality and Relevance
- Interests of research funders and research organisations

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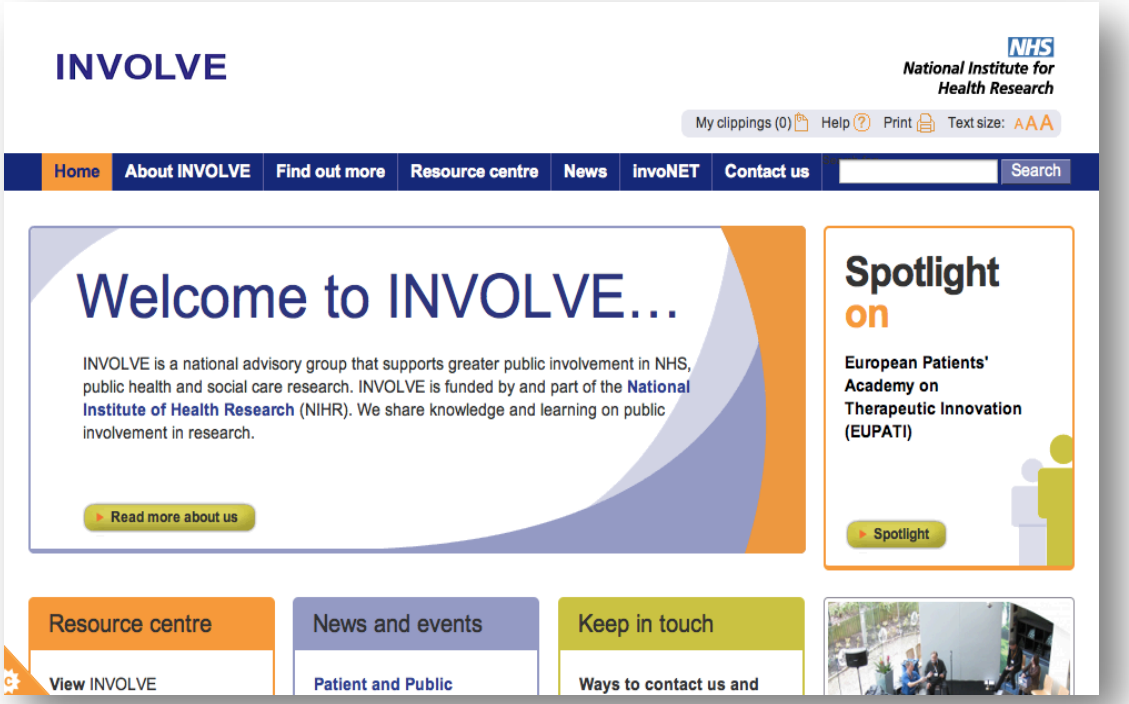
Advice, information and support

- INVOLVE
- Research Design Service



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Advice, information and support

- BRC & PERC PPI Manager
- PERC PPI Officer for HPRUs and DEC
- Imperial PPI/PE Virtual Network
  - PPI/PE Champions within each team

- PPI Training/Workshops
- Individual support and advice
- PPI Resources
  - Rewards and recognition guidance
  - PPI Grants

- BRC PP Panel
- Wider PP Panel

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Thank You & Questions

Please contact:
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NIHR Imperial BRC and PERC
Email: mboudion@imperial.ac.uk
ppi@imperial.ac.uk

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NIHR Imperial Biomedical Research Centre (BRC)

NIHR Imperial Biomedical Research Centre (BRC)

- Dr Paul Craven, Head of Clinical Research Operations

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Healthcare Translation Background: AHSC and AHSN

AHSC
Focuses on discovery science and early stage translation

AHSN
Larger-scale delivery of evidence based practice into healthcare

Discoveries arising from basic and applied research

Developing innovation and collaboration with industry

Foster research and participation

Innovate through adoption and diffusion

Enhance wealth creation and industry engagement

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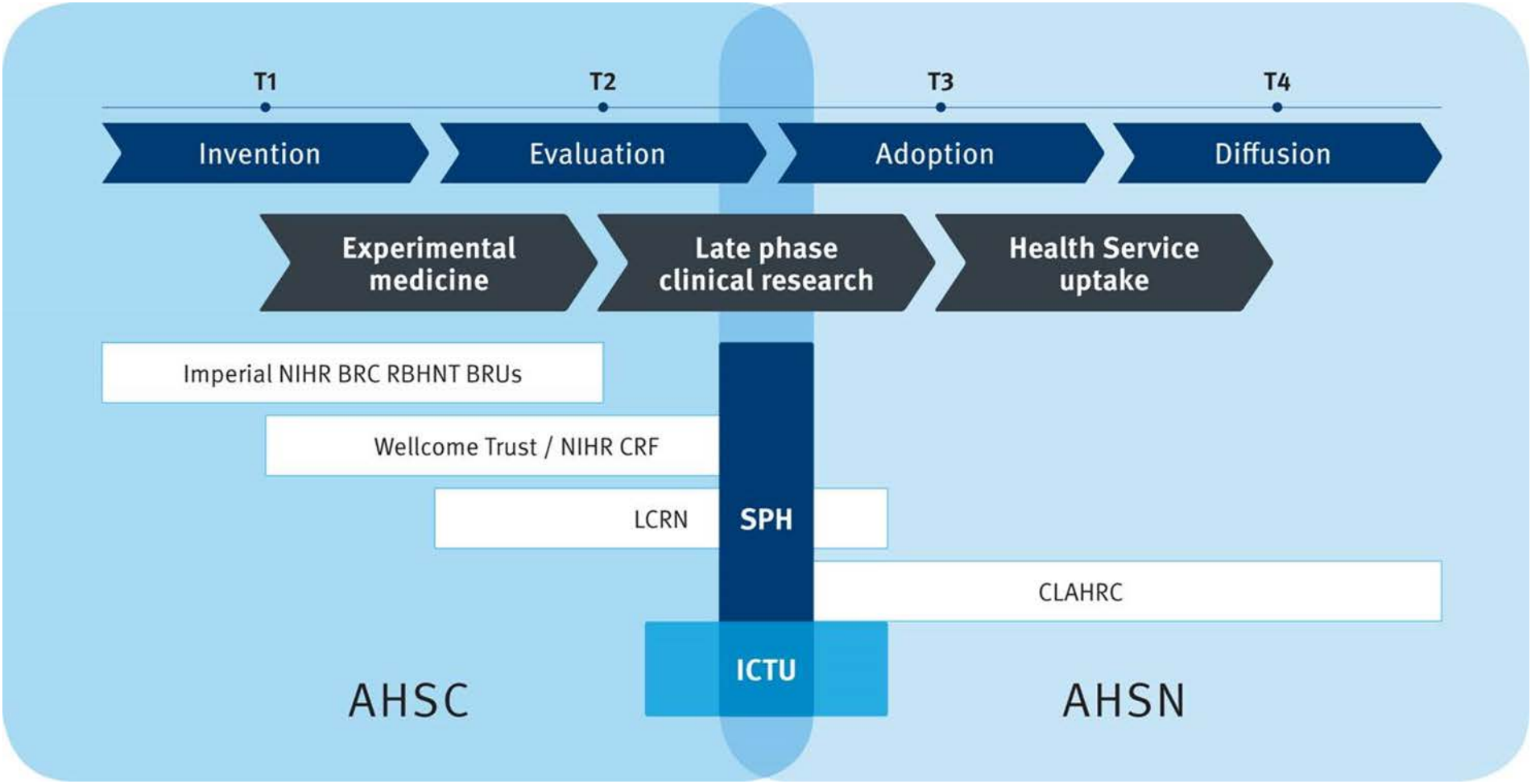
NIHR Infrastructure @ Imperial



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University – NHS Partnership

Faculty of Medicine advances clinical practice by ensuring the translation of our pioneering basic research.

Close collaboration with **Faculties of Engineering** and **Natural Sciences** and the **business school.**

Close collaboration with AHSC, transforming health outcomes utilizing research excellence from across faculties.

Support **multidisciplinary academic collaborations** and **industry partnerships** which deliver new tools, products and innovations.

Faculty of Engineering

Business School

Faculty of Medicine

Faculty of Natural Sciences

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University – NHS Partnership

WHY?

- Identifying and addressing unmet clinical needs
- Access to patient cohorts and the patient ‘voice’
- Link to clinical practice and pathways

HOW?

- AHSC – joint management & executive structures / aligned strategies
- Joint appointments / R&D Directorate
- ICHT Divisional research structures
- BRC Themes ‘map’ to ICHT Divisions

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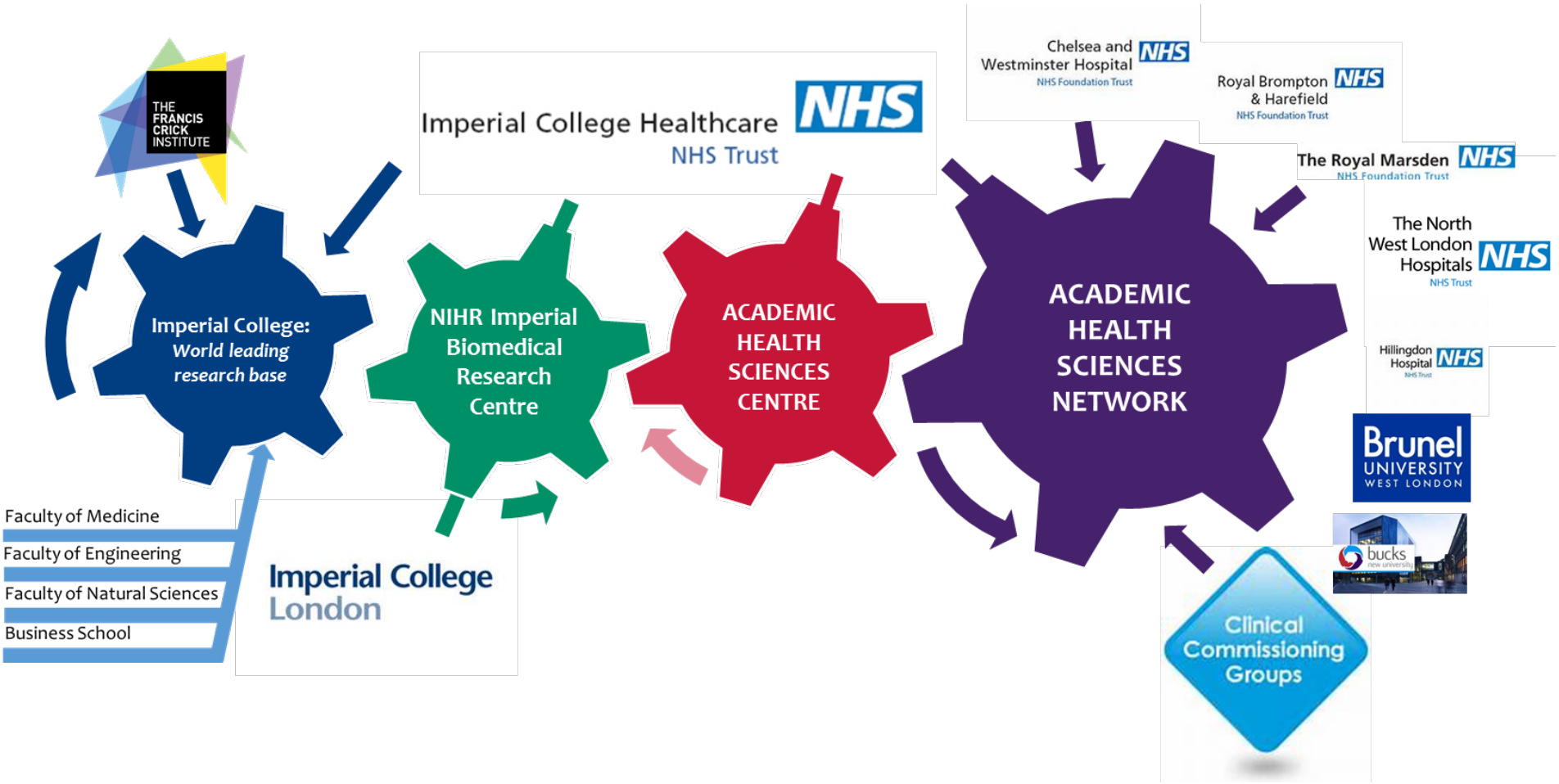
Fitting It All Together



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Intro to BRCs

- 2006/7: launch of NIHR & 1st round of BRCs (Culyer replacement)
- 2011/12: 2nd round (year 5) / 2017/18: 3rd round
- Infrastructure funding / 5-year biomedical research programmes
- Partnerships between NHS Trusts and universities (£800m DoH)
- Experimental medicine / first-in-human / proof-of-concept
- The aims of NIHR BRCs are to:
  - drive innovation in prevention, diagnosis and treatment of ill-health
  - translate advances in biomedical research into patients benefits
  - provide a key component of the NHS contribution to our nation's international competitiveness by making the best Centres even better

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NIHR Imperial BRC

- £113m over 5 years
- 8 Research Themes (Brain Sciences, Cancer, Cardiovascular, Immunology, Infection, Metabolic Medicine, Early Life Health, Surgery & Technology)
- 4 Cross-Cutting Themes (Imaging, Biobanking, Genomics, Molecular Phenomics)
- NHS Support
- Core Facilities & Services
    - Trials Unit
    - Tissue Bank

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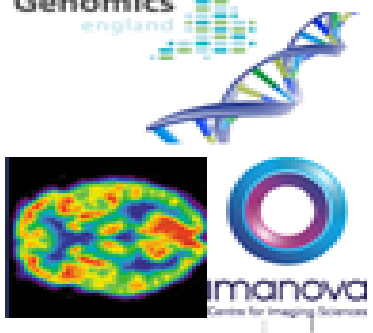
Overall Structure

NIHR Imperial Biomedical Research Centre
Translating research into patient benefits

Joint Translation Fund (pipeline / devolved funding streams / FoE / FoNS)

Institute for Translational Medicine & Therapeutics

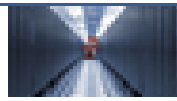
Genomics england



Imperial Clinical Research Facility

Health Informatics Collaborative

Imperial Clinical Trials Unit



Population Health & Bioresources

Patient Experience Research Centre

Clinical Academic Training Office

NHS Support Services

THEMES	PROGRAMMES (tbc)
Infection	• Infection • Anti-microbial resistance • Respiratory infection • Vaccines
Immunology	• Rheumatology • Renal medicine • Gastro – hepatology • Haematology (non-malig)
Brain Sciences	• Traumatic brain injury • Neurodegeneration • Stroke • Neuropsychopharmacology
Cancer	• Cancer • Haematology (malignant)
Cardiovascular	• Vascular sciences • Cardiac regeneration • Engineering & Comp Sci
Surgery & Technology	• Surgical robotics & allied technologies • Diagnostics & sensing • Innovation & service delivery
Metabolic Medicine	• Diabetes • Obesity • Endocrine • Nutrition
Early Life Health	• Paediatrics • Women's Health • Neonatal Medicine

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NIHR Imperial BRC: Nurturing a 'Pipeline'

- Use central budgets to support new projects
- Contribute to Imperial Confidence-in-Concept scheme
  - Encourage cross-Faculty proposals
  - Commercialisable potential
  - Unmet clinical need
  - Patients / volunteers
- ITMAT (Institute of Translation Medicine & Therapeutics)
  - Projects take advantage of BRC investment in technology platforms (cross-cutting Themes)
  - Hypothesis-driven / promising pilot data
- Training schemes (Chain-Florey fellowships)
- IMANOVA co-funding for PET imaging pilot projects

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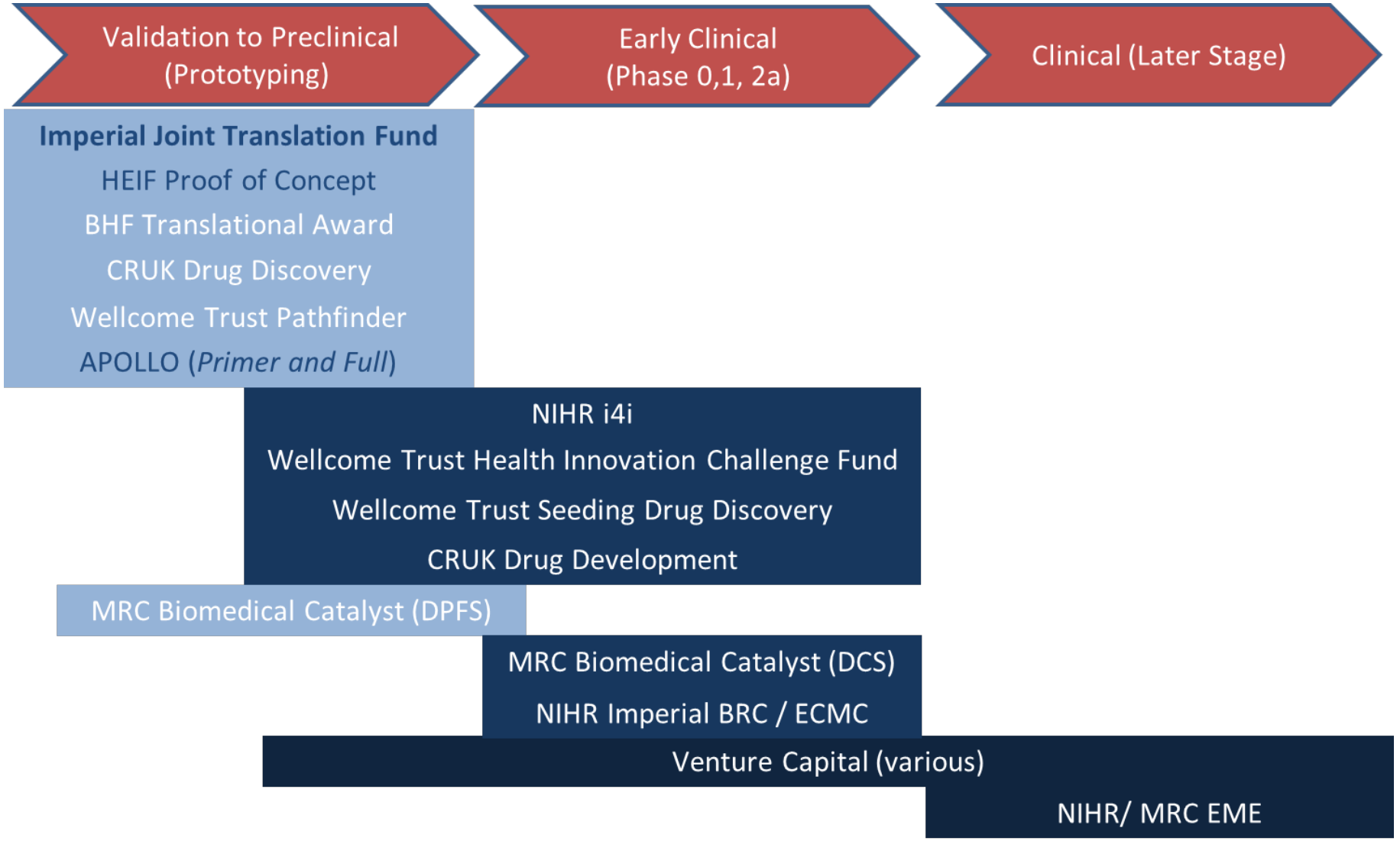
Translational Funding Schemes



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NIHR Imperial BRC: Translational Example

- The Intelligent Knife (i-Knife)

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ICHT Divisional Research Management

ICHT Divisional Research Management

- Dr Paul Craven, Head of Clinical Research Operations

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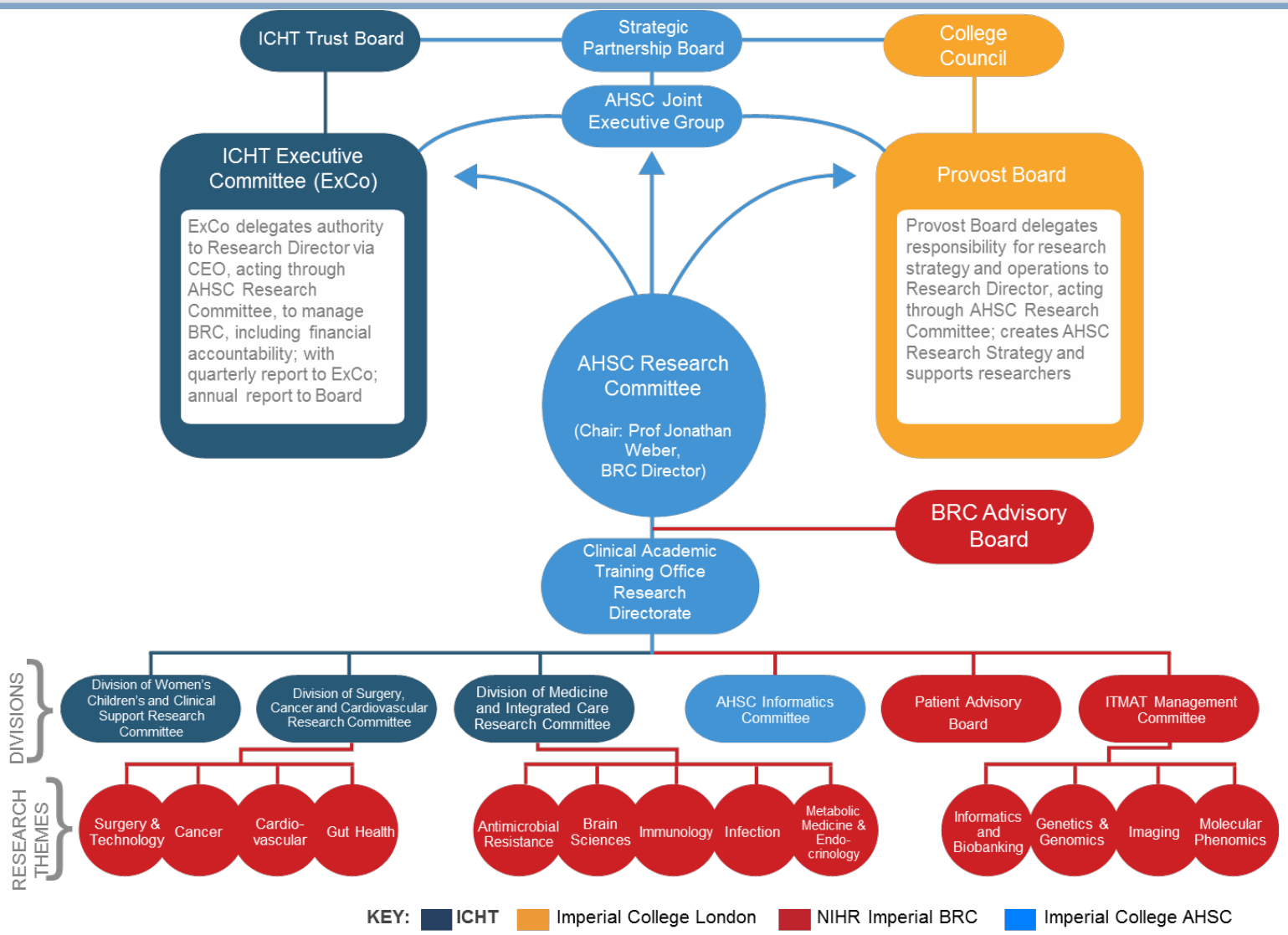
Overall R&D Governance across Imperial AHSC



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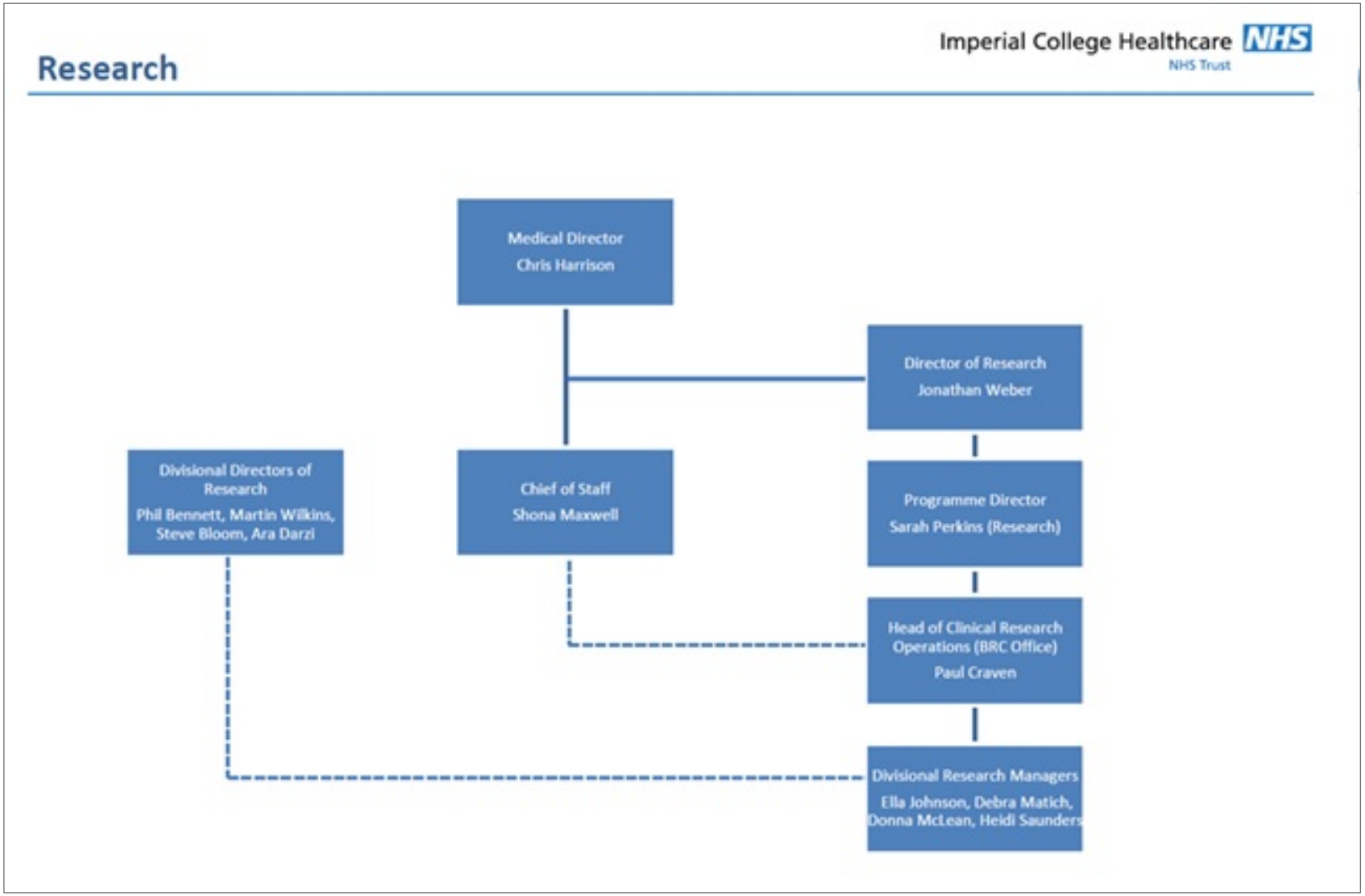
R&D Governance in ICHT



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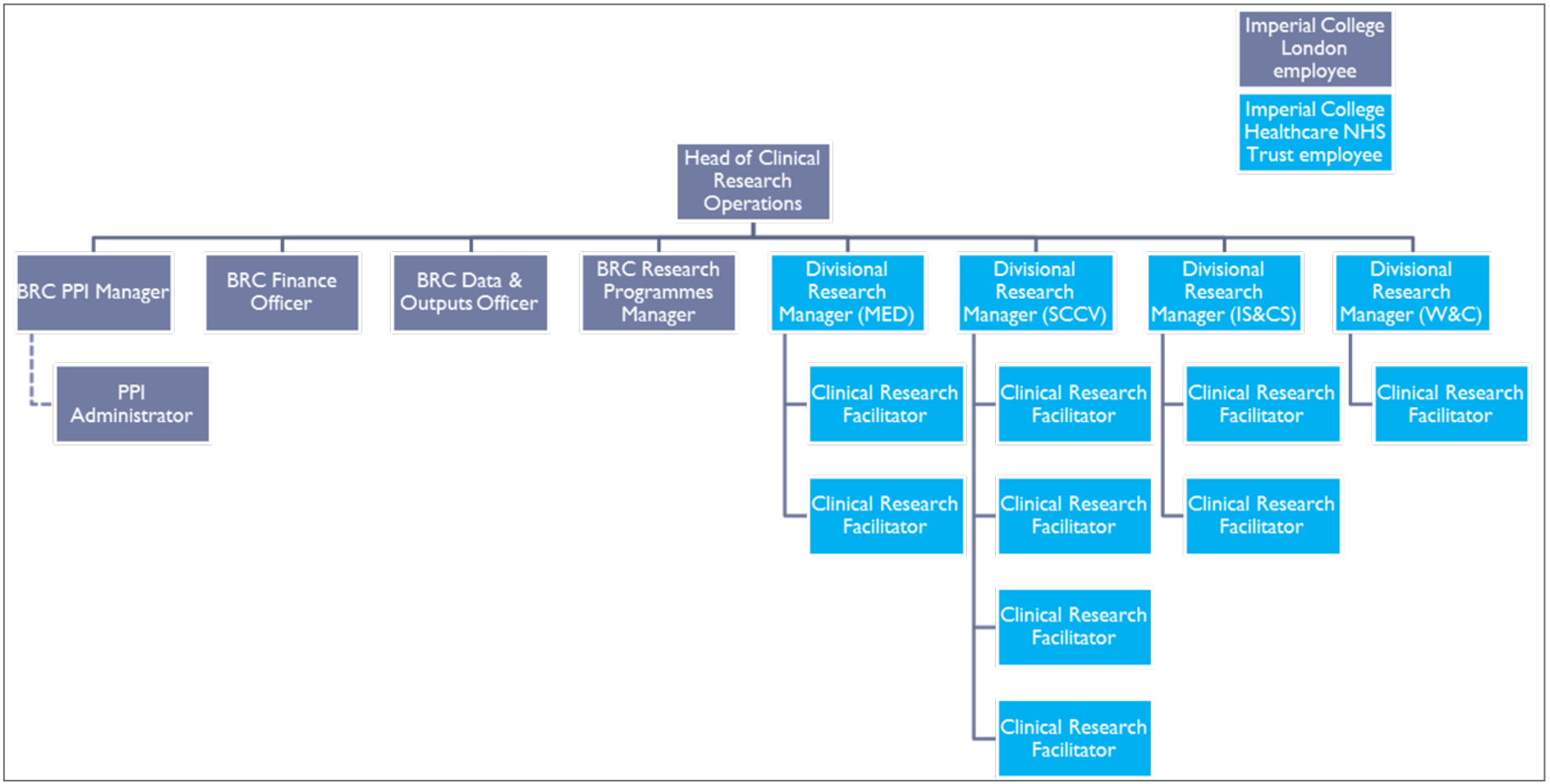
Joint Working Across NHS and University: Clinical Research Operations Office



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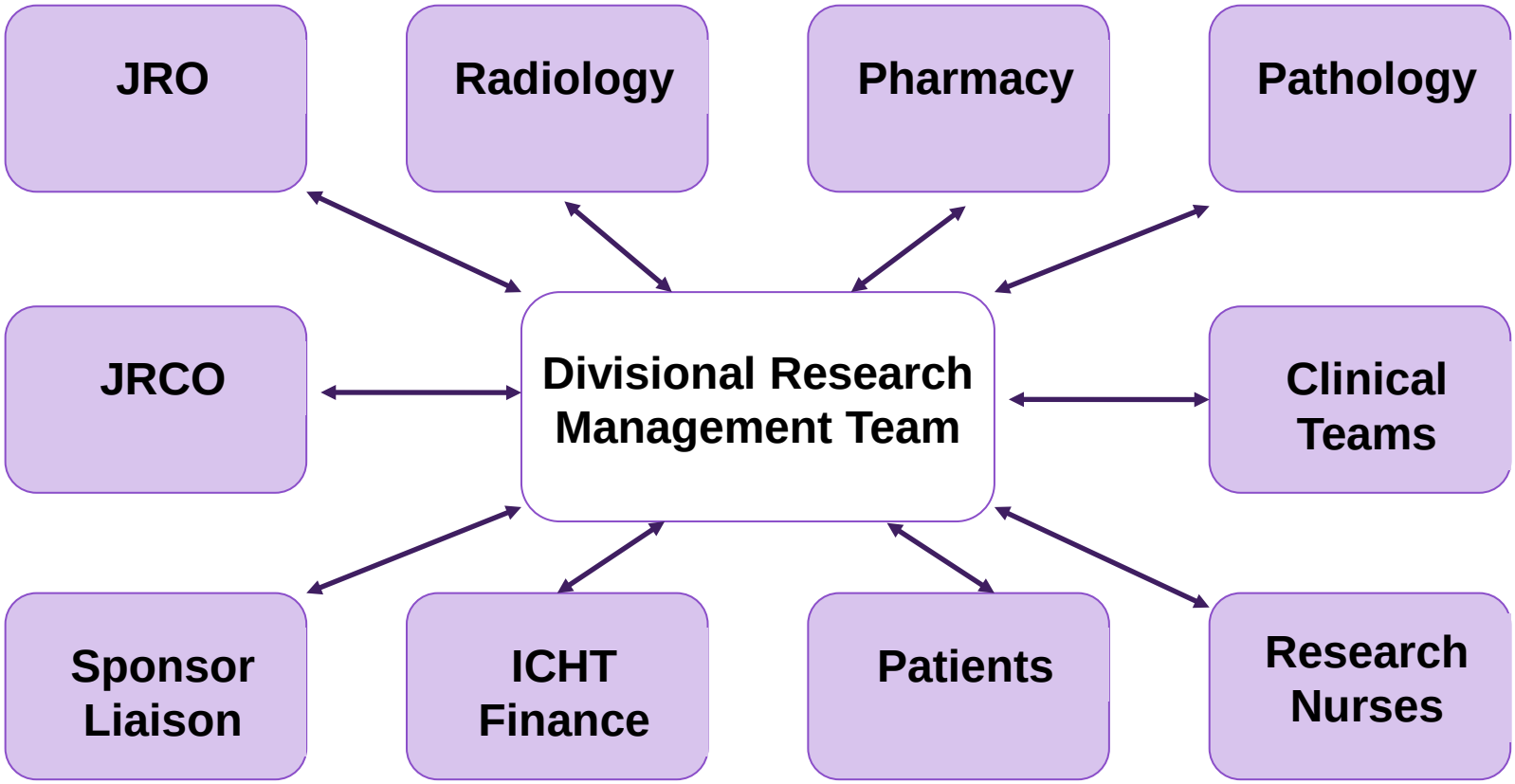
Divisional Research Management: Study Feasibility



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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.

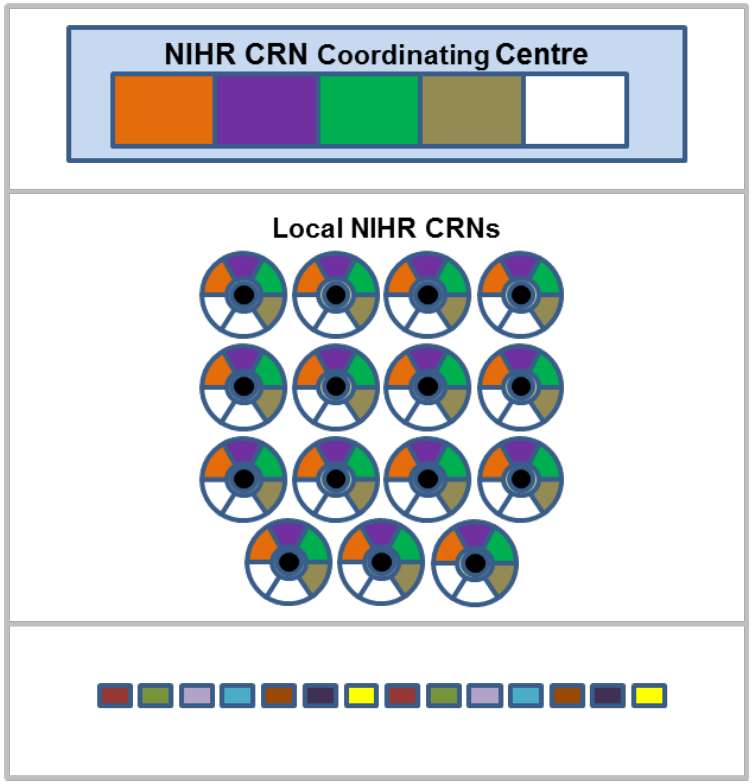
- Contract research
- Legal/management responsibility taken on by sponsor
- Standard contract and costing mechanisms

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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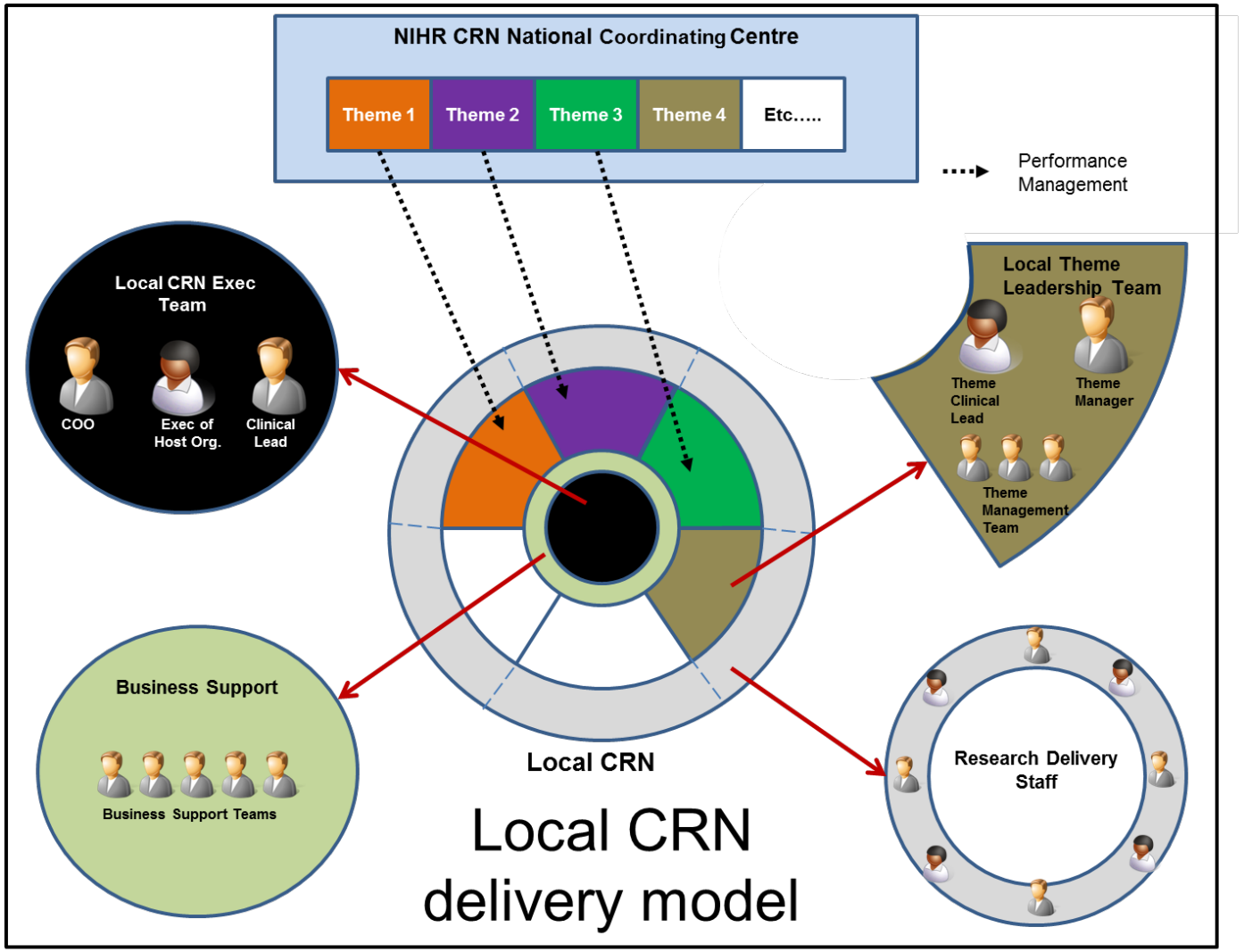
NWL Clinical Research Network



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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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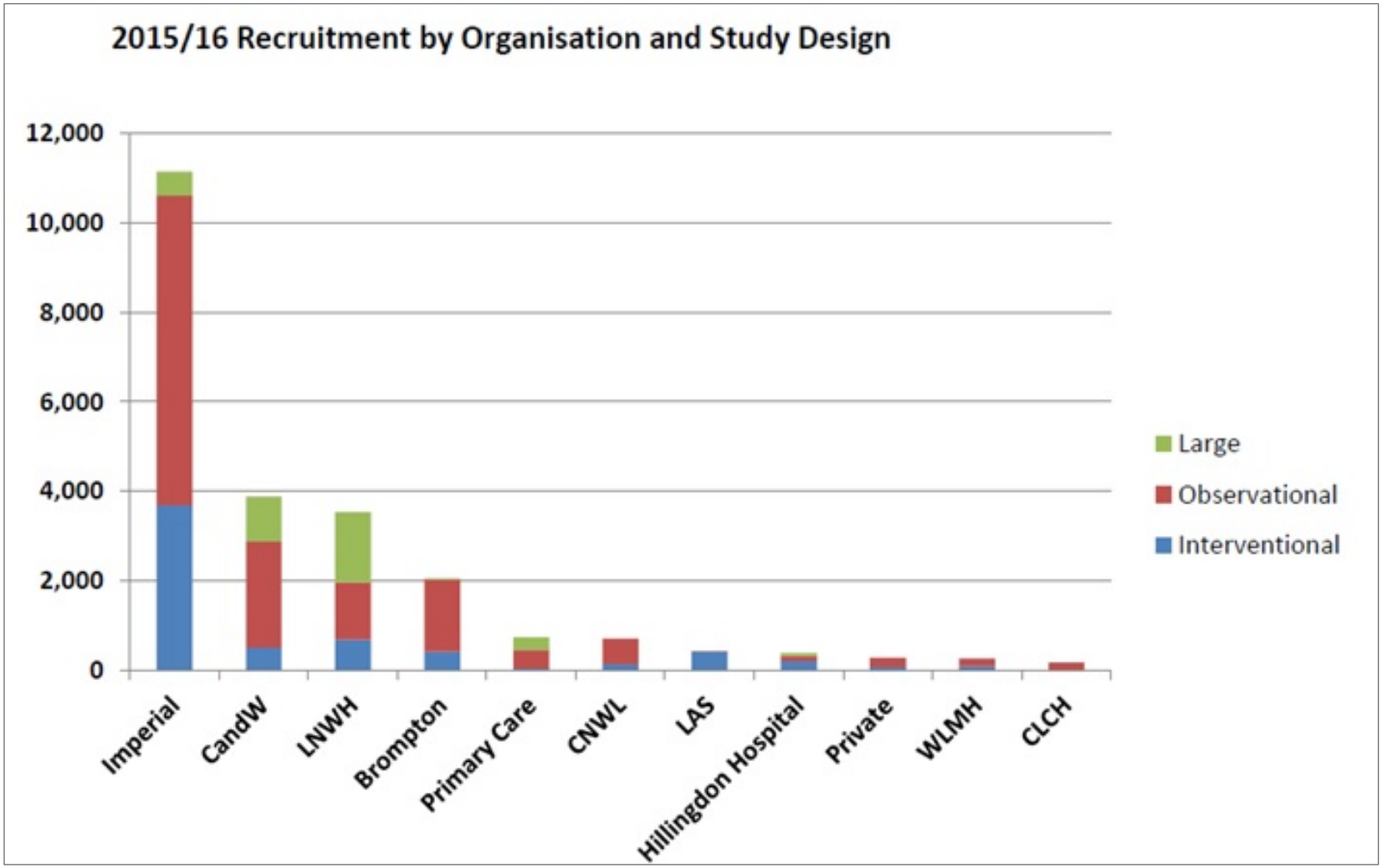
ICHT Performance in NWL CRN



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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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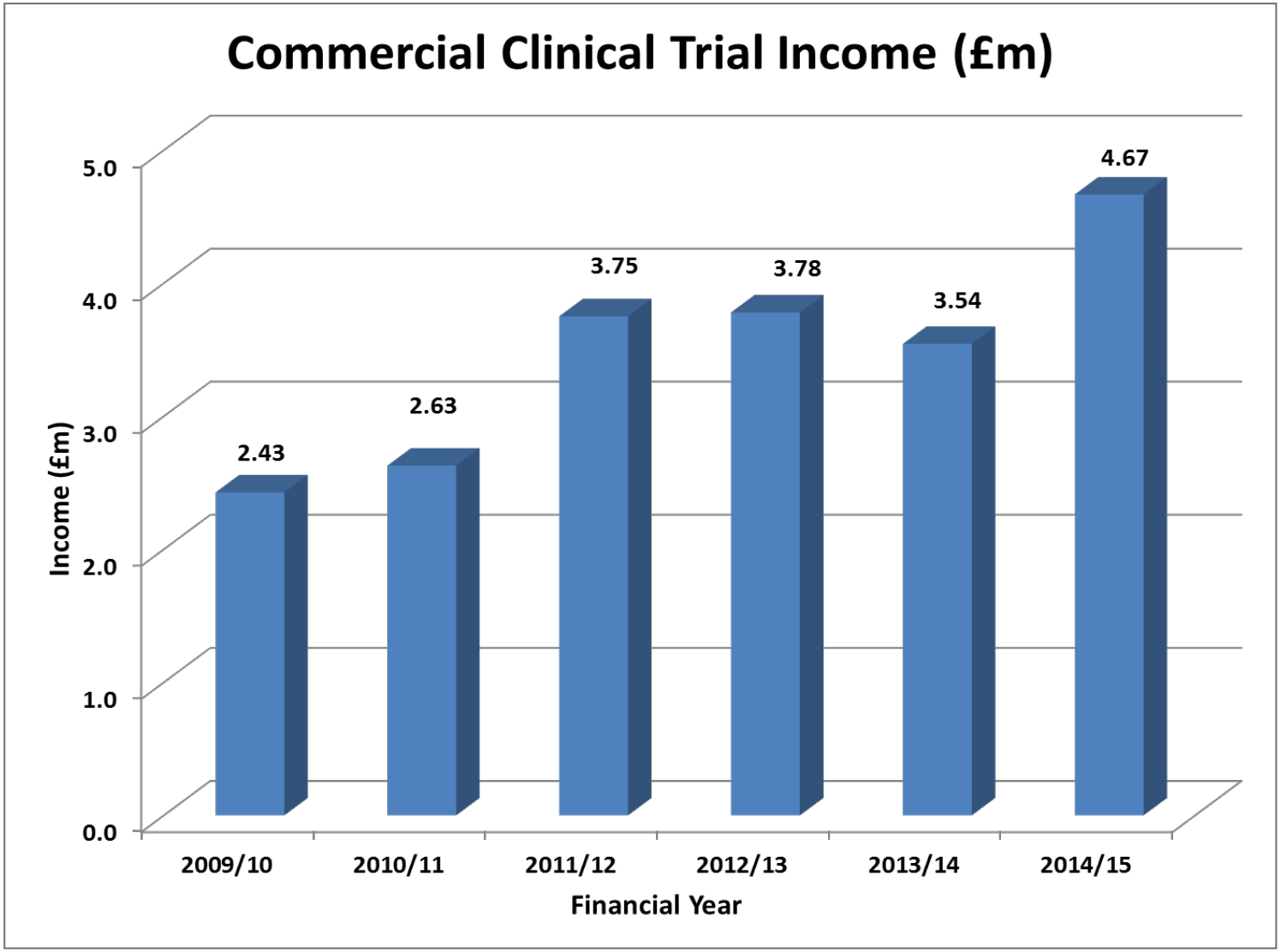
Commercial Trials Income



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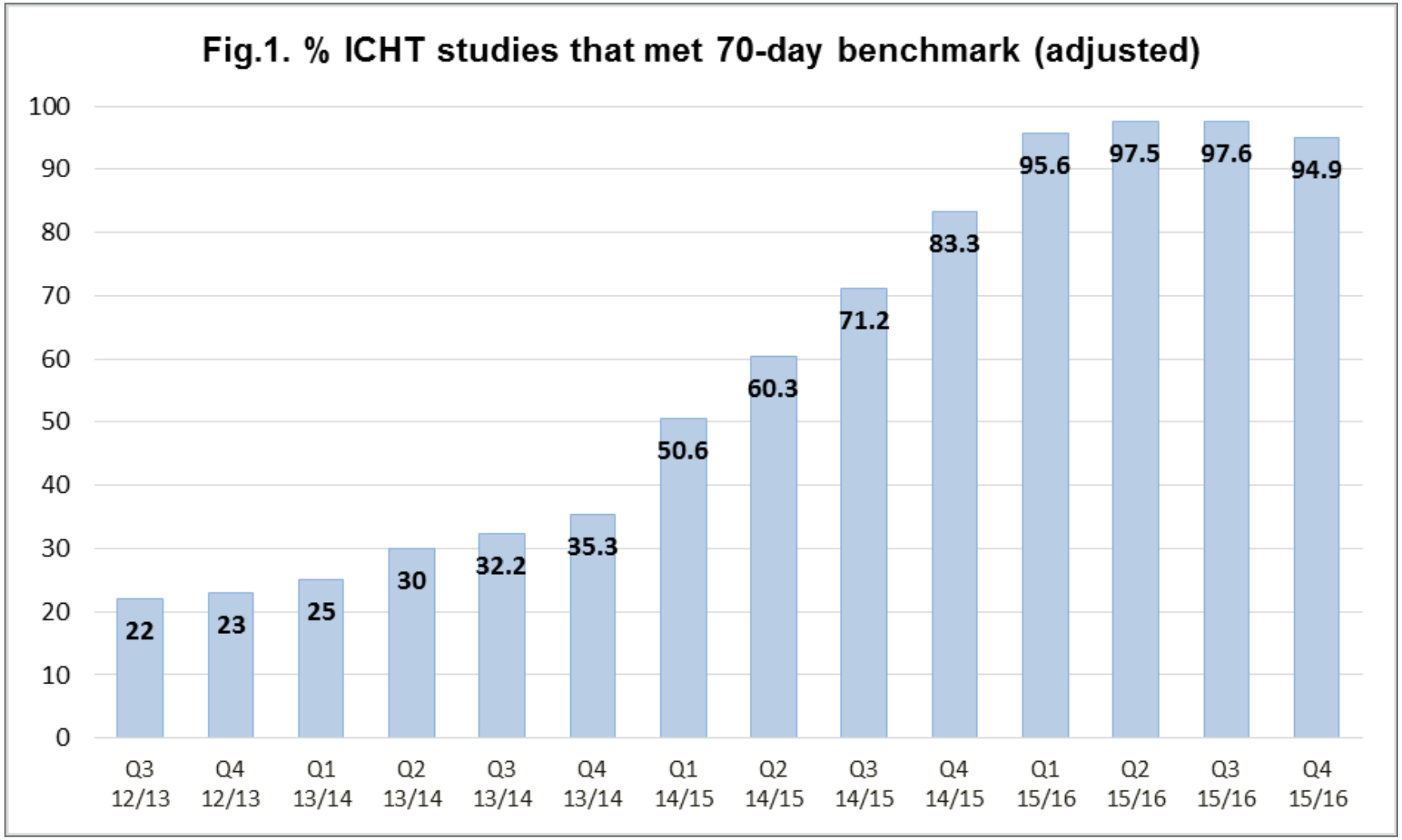
NIHR Performance Metrics: Initiation



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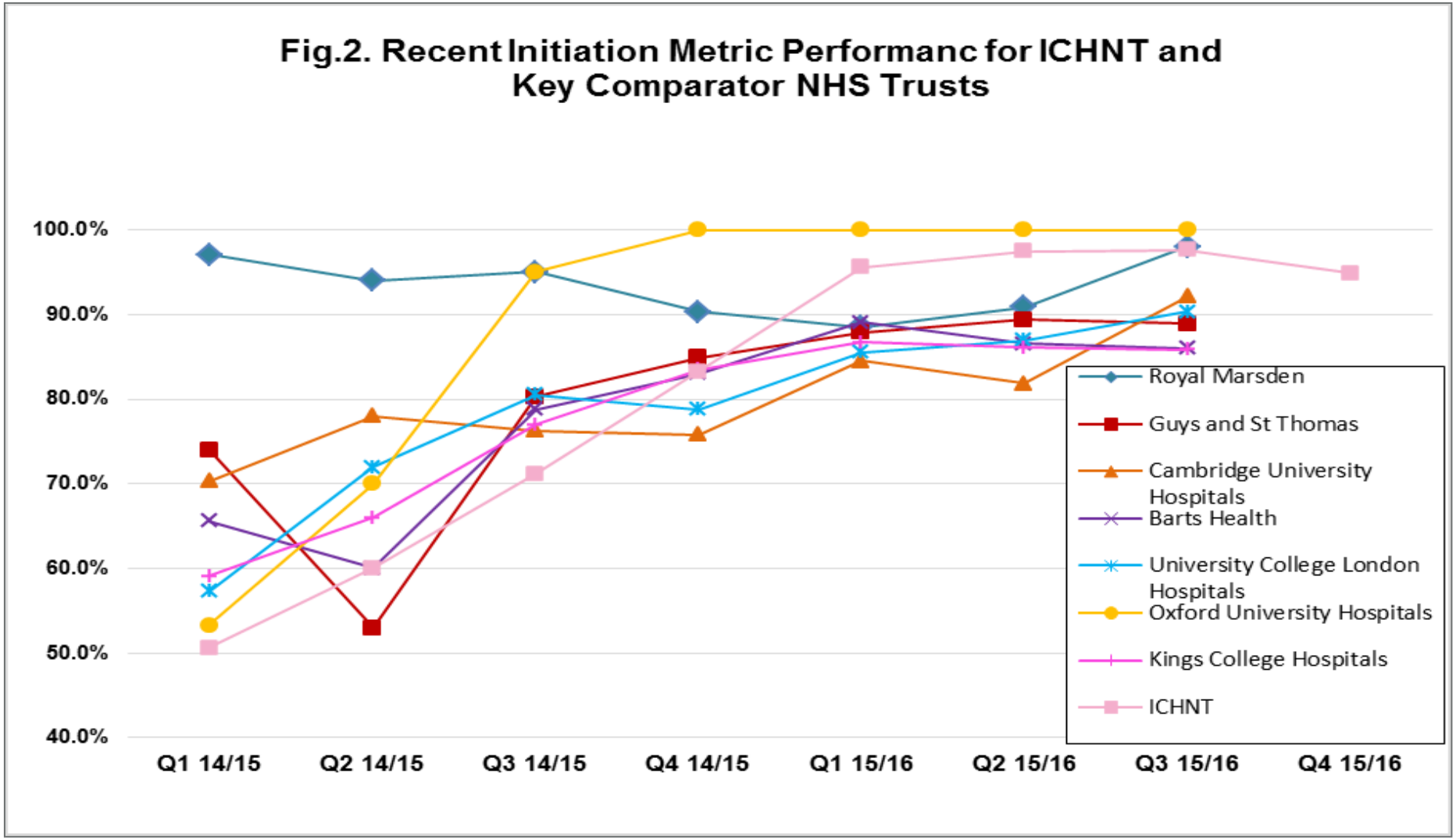
NIHR Performance Metrics: Initiation



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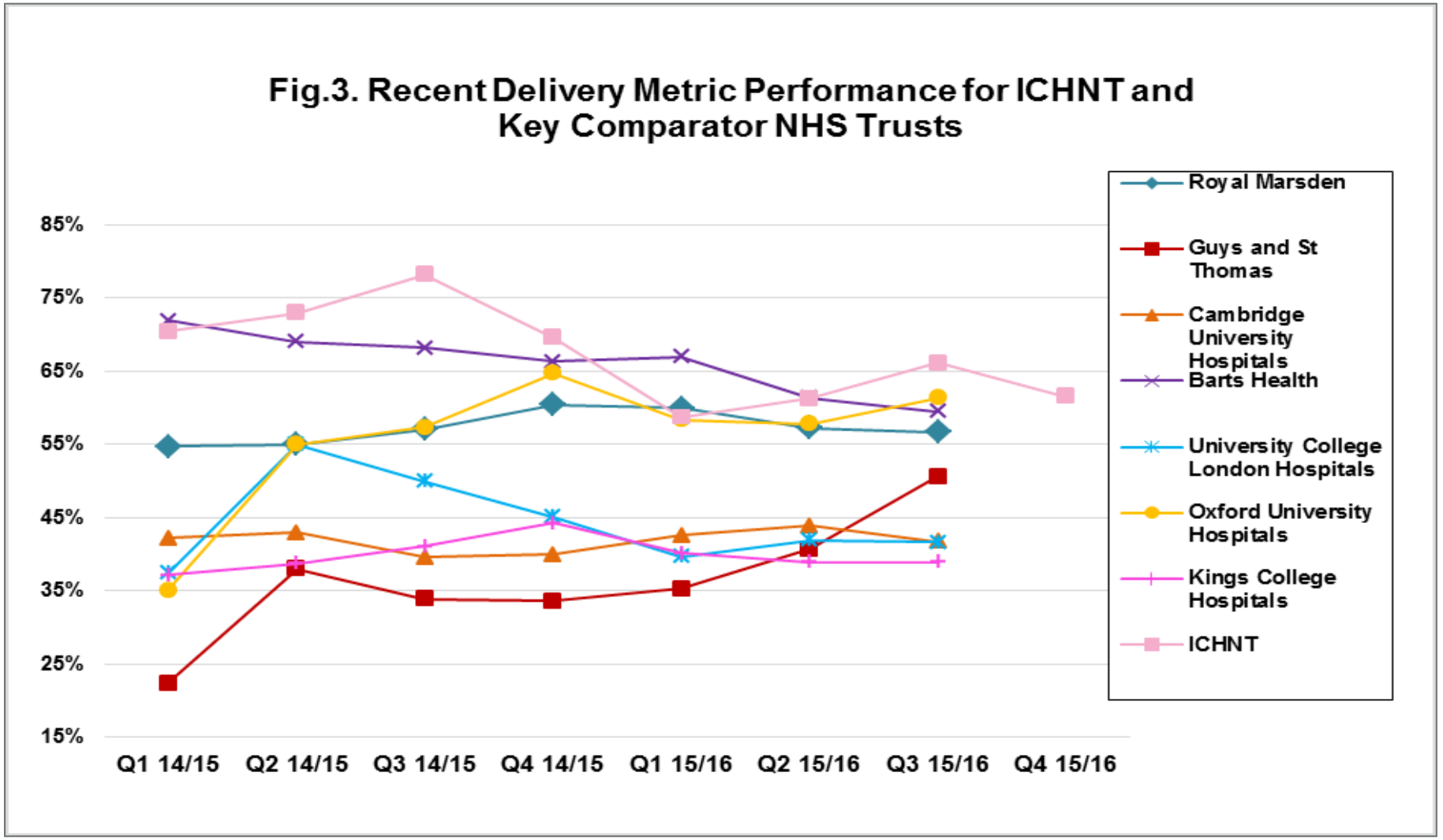
NIHR Performance Metrics: Delivery



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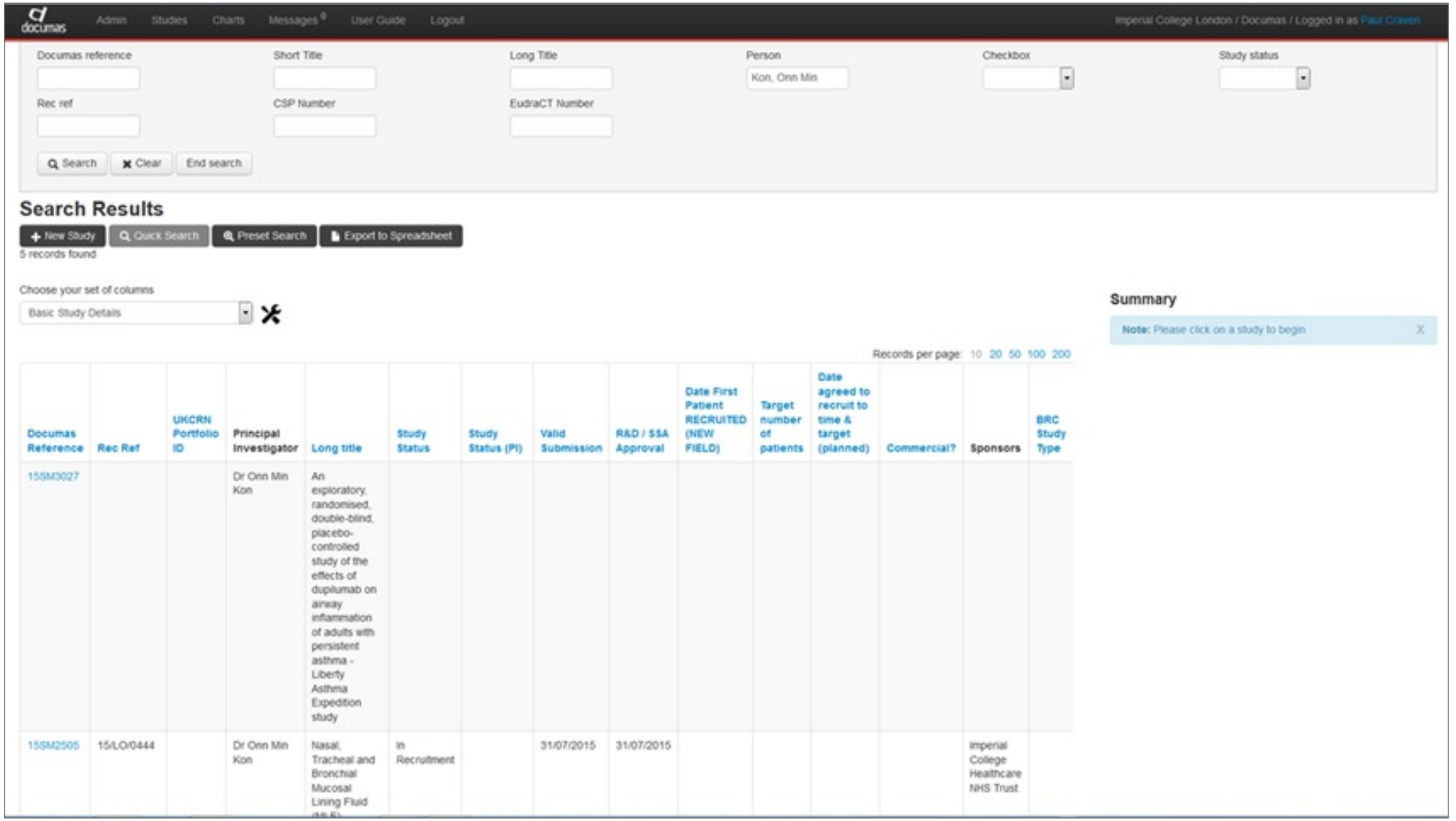
DOCUMAS Clinical Trials Management System



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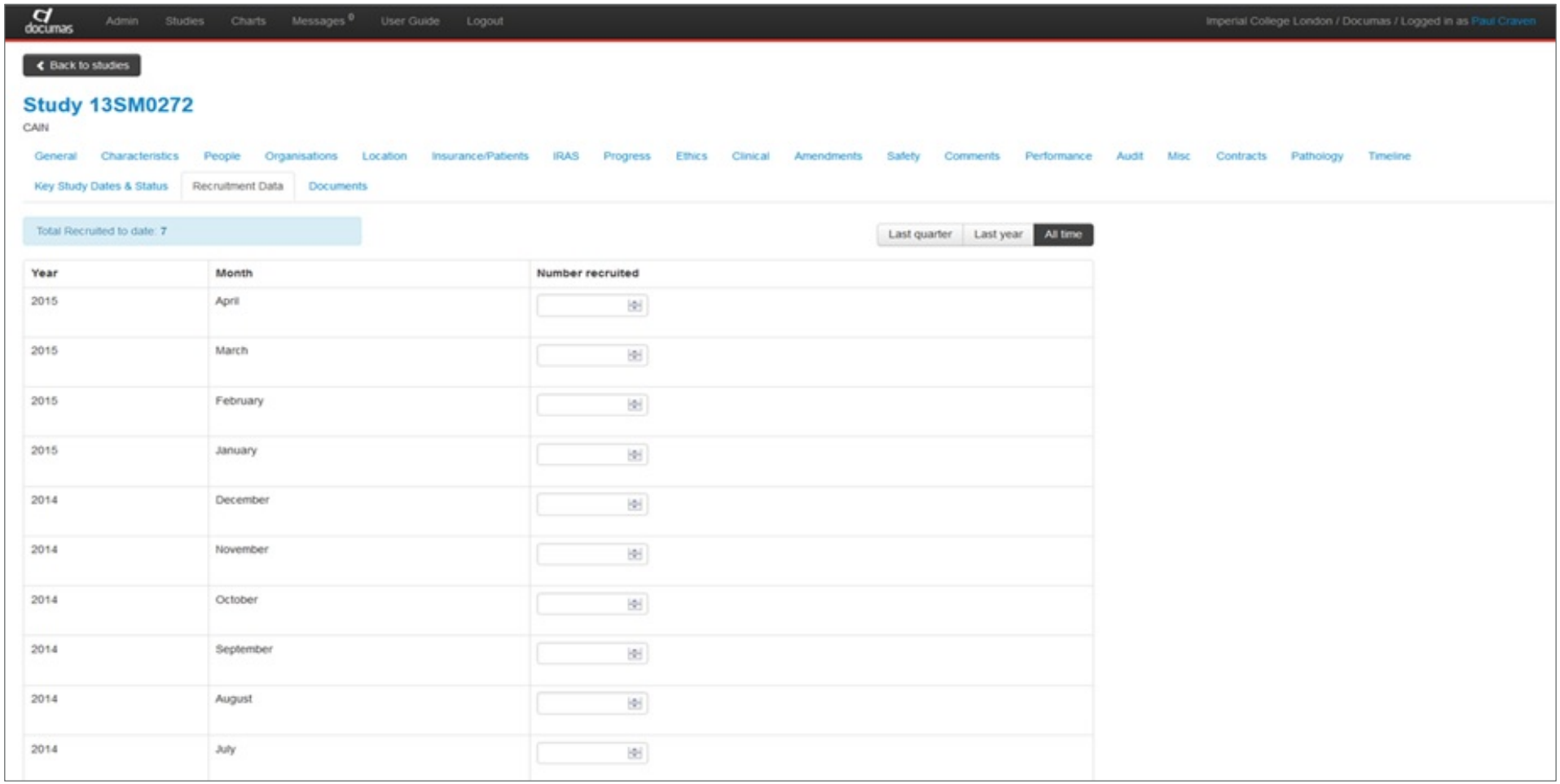
DOCUMAS Clinical Trials Management System



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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

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QUESTIONS