



National Institute for Health Research Coordinated System for gaining NHS Permission NIHR CSP

Ian Goodall

Karen Matthews

UK Clinical Research Network

Chris Keane

Infonetica

NIHR CSP - Background

- National R&D Strategy *Best Research for Best Health* identified unnecessary bureaucracy as a major barrier to clinical research
- UKCRN charged with developing a Coordinated System for gaining NHS Permissions (CSP)
- CSPU in UKCRN CC will work with CLRN, Trusts, Sponsors, Investigators and Industry
- Aim is for all potential portfolio studies to go through CSP

Participants in NIHR CSP

- CSP Unit (CSPU)

Coordinates the receipt of study, informing CLRNs involved. Carry out **global** governance checks with regards to documentation that do not require specialist RM&G knowledge.

- Lead CLRN

The nominated CLRN to carry out the **global** governance checks which require specialist RM & G knowledge. This will usually be the CLRN where the Chief Investigator is based. May be occasions when this is not assigned on the basis of CI due to resources.

- CLRN

Performs the **local** governance checks facilitating engagement with the NHS organisation which is a site within the study. Instrumental in communicating with the NHS organisation to facilitate gaining their permission.

- NHS Organisations

Their function is to grant NHS permission.

Study Sites

- Single site studies
- Multi site studies within a single CLRN (single CLRN study)
- Multi site studies

Governance Checks on Studies

- Global Checks (once only) : Undertaken by CSPU and Lead CLRN on behalf of all sites (Lead CLRN only if study is single centre or single CLRN)
- Local Checks (required at each site) : Undertaken by CLRNs or a Lead CLRN (single centre or single CLRN)

NIHR CSP – The Process

- Applicant access to CSP
- Study review
- Integration of CSPU, Lead CLRN and CLRNs
- Gaining NHS permission

IRAS is the starting point for CSP



Progress of a multi centre non-commercial study through CSP (1)

CI completes PAF for new study within IRAS

Portfolio Team assesses eligibility

CSPU assigns Lead CLRN

CI submits main R&D form to CSP ReDA

CSPU identifies participating CLRN

CSPU, Lead CLRN and CLRN start governance checks

SSI forms submitted to CLRN

All checks complete

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Progress of a multi centre non-commercial study through CSP (2)

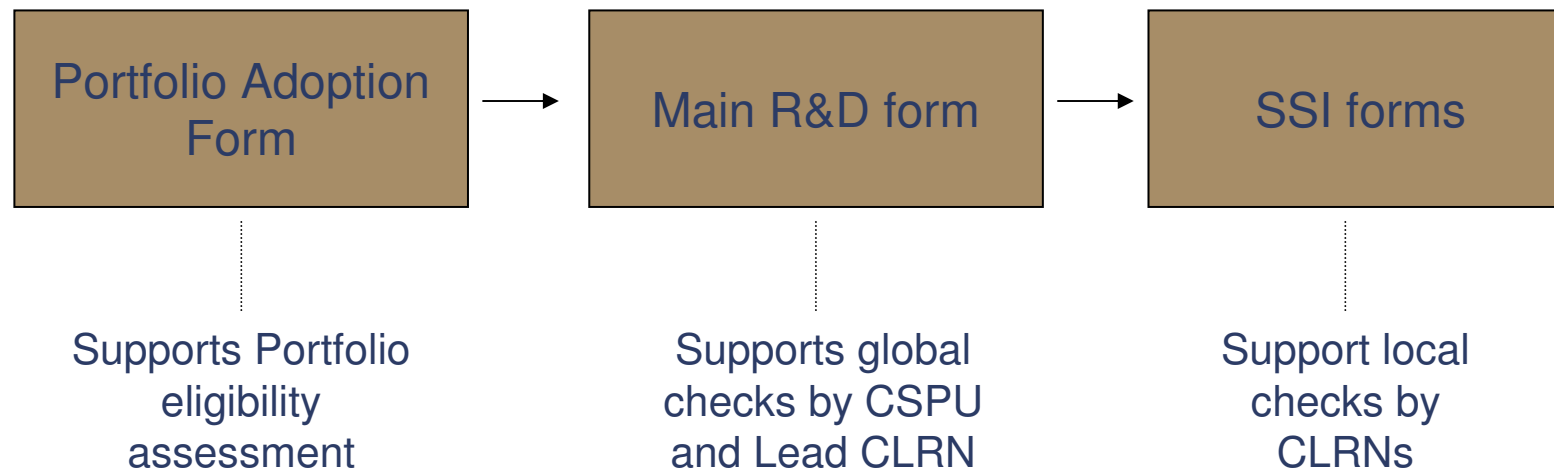
CSPU Sign-off (first site)

CLRN produce Governance Report

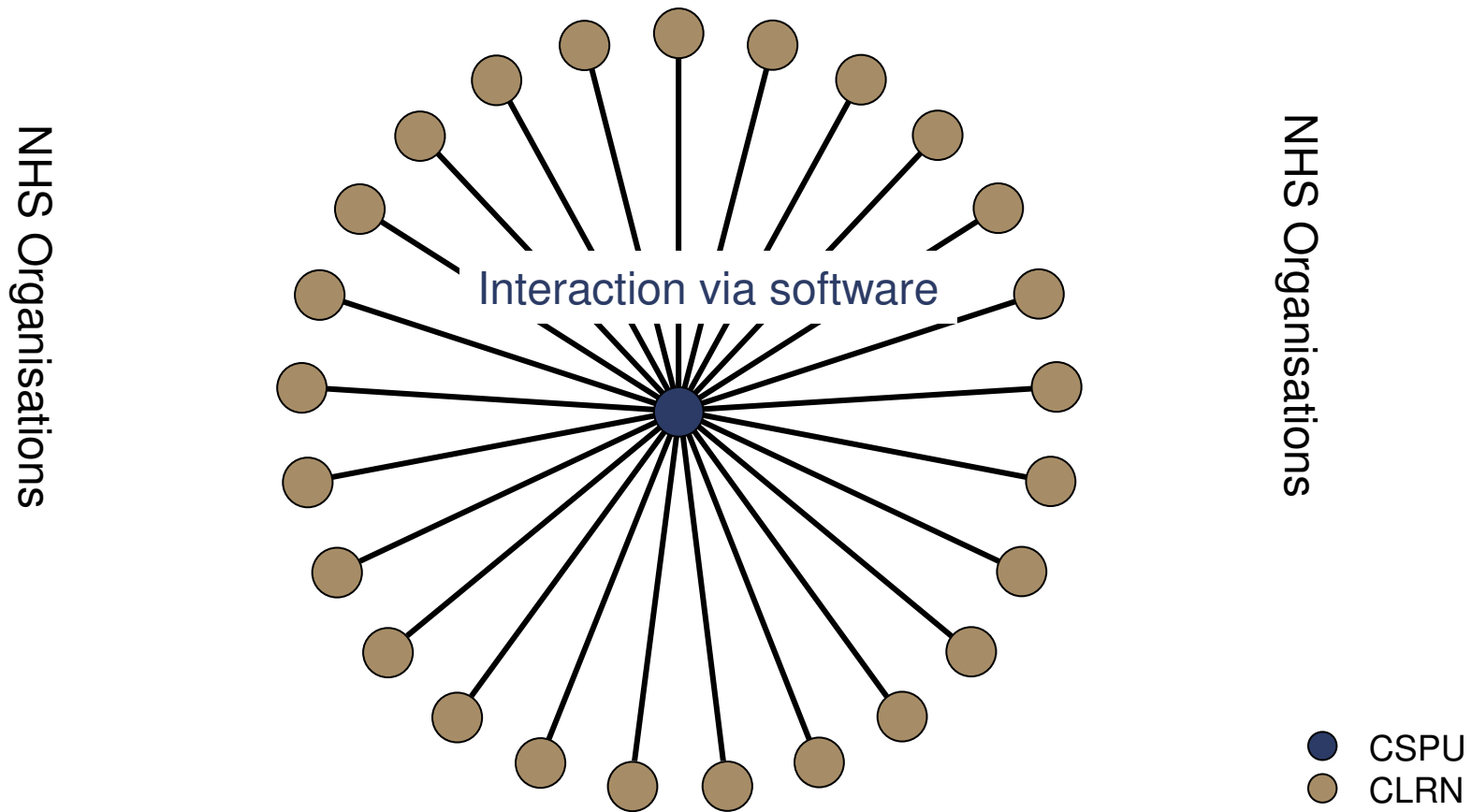
CLRN seeks NHS permission (first site)

CSPU Sign-off for other sites

CSP Submissions within IRAS



CSP ReDA Linking CSPU and CLRNs





CSPU – Studies Page

NHS
National Institute for
Health Research

- *Live demonstration of CSPU Studies page*



CSPU – Allocation of Study to Lead CLRN

NHS
National Institute for
Health Research

- *Live demonstration of CSPU Study allocation page*



Lead CLRN and CLRNs – Acceptance of Study



- *Live demonstration of CLRN study acceptance*



Lead CLRN and CLRNs – Information Page



- *Live demonstration of CLRN study information page*



Governance Checks Page

NHS
National Institute for
Health Research

- *Live demonstration of Governance checks page*



Lead CLRN – Addition of Stakeholder



- *Live demonstration of addition of stakeholder, e.g. researcher*



Reminders

- Study notes are recorded on the system
- Emails are sent (e.g. to Investigators) within the system



Reminders Page

NHS
*National Institute for
Health Research*

- *Live demonstration of Reminders page*



CSPU Sign-off

NHS
*National Institute for
Health Research*

- *Live demonstration of CSPU sign-off*



CLRN – Governance report

NHS
National Institute for
Health Research

- *Live demonstration of production of Governance Report*



Document Repository

- Contents
- Access
- Future plans

Benefits of CSP

- Streamlined and standardised approach
- Minimised administrative burden
- Quality assurance
- Central electronic repository for documents
- Reduced duplication
- Central register of researchers, funders, etc.
- Monitoring of checks process
- Work done on studies that are not adopted passed over to CLRN



Any questions?

**General queries regarding NIHR CSP
should be sent to**

csp@ukcrn.org.uk