

NIHR/UKCRN IS Programme

Responses to Comments Received Regarding Documents Published in January 2007

Key P = Portal R = R&DMIS

Doc	Comment	Response
P	<ul style="list-style-type: none"> Is there a payment or a subscription fee for portal use by Welsh organisations? What are the list of portal resources? Will there be a link to Acrobat? Information ownership/maintenance Need for web access by minimal IT systems Portal reliability – requires backup, needs anti-abuse, spyware protection etc, identity theft threat, systems capacity, training and education. 	<p>The portal and the R&DMIS will be free of charge for users.</p> <p>Portal has had a Security Review that addresses these issues, the same type of review will be used for the R&DMIS</p> <p>Portal training needs are being addressed as part of the roll out</p>
R	<ul style="list-style-type: none"> “Excellent, visionary proposal” Wales R&D wish to be involved Needs streamlined R&D processes, accessibility, security, training, education Needs to cover smaller scale and single site studies, Regulators may require complete packages before approval Metrics may imply league tables – which could be considered negative, Many issues to resolve for R&DMIS 	<p>While the NIHR programme is focused on England information will be made available for Welsh Trusts and Wales-based organisations (and those in the other countries of the UK) and the programme is working closely with Professor John Williams and his team to ensure compatibility and shared benefits based on their appropriate financial contribution to the programme.</p> <p>The full definition of requirements for the R&DMIS is about to start. The comments made will be considered as part of that process.</p>

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P	<ul style="list-style-type: none"> • The Portal is very comprehensive but other systems also exist – the portal must link with them • Can R&D staff become involve with portal content group? Will the portal replace NRR? • Will the portal mean that the Department of Health can collect information directly and therefore there will be no requirement for multiple reports? • The Document repository is an excellent idea • The Research Passport is not clear – some researchers will not have passport • R&D office staff (not just R&D manager) will need access to systems 	<p>The portal will act as the presentation, document storage, collaboration and authentication base for a number of systems, of which R&DMIS will be a major example.</p> <p>The portal will not replace the NRR, (which is being phased out) but the R&DMIS and other systems will include its functionality and manage essentially the same data.</p> <p>Reports to DH will be facilitated trough the R&DMIS, not primarily through the portal, although the functionality that will allow such reporting will not be available in phase 1 of the R&DMIS.</p> <p>Accepted that Research passport will not provide complete coverage, but it has the potential to make accreditation of researcher where it does apply much quicker and easier. While the implementation of research passports is currently outside the scope of the NIHR IS Programme the portal and the R&DMIS will eventually use the Research Passports to aid with the setting up of user accounts and authentication.</p> <p>Staff who work in the R&D office may well need access to systems. We need to establish whether their level of access should be the same as the manager or spoke more restricted level</p>

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P+R	<ul style="list-style-type: none"> Two identical comments on P/R. The Scope appears to be just health research. If scope is to include social care then big consultation may be required similar to the Cooksey review? 	<p>This issue will be addressed by the Programme Board which will meet for the first time in May 2007.</p>
R	<ul style="list-style-type: none"> Can you add a facility to search on Trust/PCT/Hospital/Surgery etc. Please be more clear about what 'R&D manager' means The system must allow for users to belong to more than one class Need definition of external interfaces The user guide needs to include content from other user perspectives What about a research governance wizard? There must only be one system for portfolio and non-portfolio studies 	<p>This is useful input to the requirements for the R&DMIS and work is currently starting on this.</p> <p>Users can belong to more than one class.</p> <p>R&DMIS plans do, effectively include a research governance wizard, at least to the extent that users will be able to use a wizard to determine what governance is required for a particular study. It might be possible to extend this to explain to the user why such governance applies.</p> <p>The portfolio functionality will be used only where portfolios are in use. There will not be two independent systems, i.e. the same methods will be used to manage a study irrespective of whether it forms part of a portfolio.</p>
R	<ul style="list-style-type: none"> CV storage will be useful Application Programming Interfaces (APIs) should be based on international standards - several specified, data structures should map to these The National School for Primary Care Research (NSPCR) has an application which should interface with NIHR systems 	<p>The definition of data standards is part of the work needed to define the design for the R&DMIS and international standards are definitely part of this. We may need to define data structures that are not currently supported by international standards, given the overall scope of the R&DMIS.</p>
R	<ul style="list-style-type: none"> This provides a good comprehensive foundation Perhaps all Comprehensive Research Centres should have a common approach 	<p>The NIHR IS team are now working closely with Andy Miller to address these issues</p>

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R	<ul style="list-style-type: none"> • Page 16 - audit trail will store logic at time of completion needs a warning to say that this may be out of date if re-visited • Use CI (Clinical Investigator) instead of “Lead Researcher” throughout • Page 16 reorganise/reword bullets • Would it be possible to link related projects together to share same documents? • Not all approvers are able to suspend approval, Users need visible clock • Page 24 - costing and pricing as UKCRN industry team? • Page 35 - Take over as well as hand over – e.g. death dismissal • Page 37 class 7 will this include R&D Managers in universities? • Page 39 modifications to external systems suggested • Page 42 add UKCRN under approvals and monitoring • Page 45 appropriate docs for regulatory inspectors • Comprehensive useful documentation, needs careful review by UKCRN 	<p>The NIHR IS team will work with Janet Messer and the NHS R&D Forum to address these issues and we will also consider re-issuing the papers to take into account the comments received here.</p> <p>The NIHR IS Programme has now been combined with the UKCRN IS initiatives to ensure that that these efforts are joined up.</p>

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R	<ul style="list-style-type: none"> • Universities do not appear to be identified in systems architecture • Research applications wizard is a good idea – it needs to include sponsorship question, and needs sponsor authorisation • Wizard must cover all variations correctly • National Advice Service is useful, but local advice is useful also • Funding wizard is good idea, and needs to refer to RDInfo etc. • There needs to be control mechanisms for funding applications - Trusts need to have control over NIHR Applied Programme Grants via the R&DMIS • Page 28 Costing templates – detailed queries are needed • A single annual progress report is a good idea but Trusts will require their own reports • Page 32 Wizards for SAE reporting are a good idea, but it needs to be able to cover the most complex cases correctly • Page 32 Links with Eudravigilance are good, but concerns about how this will work 	<p>The programme board will include a high level representative from the university community to ensure that the programme fully takes into account the needs of these stakeholders.</p> <p>In addition, as we define the more detailed requirements for systems that will precede procurement and/or system development, we will hold workshops and benefits forums with the broadest range of stakeholders to ensure that we understand and have taken into account their needs.</p> <p>We are working closely with the RDInfo Team via UKCRN.</p>
P+R	<ul style="list-style-type: none"> • The system wants at least as open and functional access as is currently provided to NRR • The system needs to search for studies in particular ways • There is a need for search functionality like PubMed 	<p>All these requirements are currently provided by the portal or in combination with the proposed R&DMIS as it is currently understood</p>

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R	<ul style="list-style-type: none"> • User requirements are based on assumption of clinical trials. Non-trials based research also important. Assumption of trials base also distorts requirements for reports etc. • Need to have flexibility into the sequence of wizard questions National Co-ordinating Centre Health Technology Assessment need to be able to commence a funding application wizard process with a 'Call for Proposals' even before the beginning described in paper, see comments for full detail – complex. Need to allow bypass of funding wizard. The URL for NCCHTA now incorrect. NCCHTA has a full costing template that they are willing to share. • Various additions to reporting requirements are necessary. NIHR programmes may also need a user type? Does monitoring for commissioners needs an API? 	<p>This is a good observation. Need to cover ALL types of research and make sure that wizards operate correctly for non-trials based research.</p> <p>The guidance given by the wizards needs to reflect the specific type of trial being considered. Establishing a complete classification of trial types is an essential first step in this process, to be followed by a definition of regulations that apply to all those types of trials. The paths through a trial may be very different depending on the type.</p> <p>The NIHR IS Programme is working closely with HTA and the other commissioning agencies to address these issues.</p>

Doc	Comment	Response
R	<ul style="list-style-type: none"> • How will R&DMIS interact with local systems? The Wizards need very careful design • Concern about clocks and baton passing from R&D Support Unit's perspective , will encourage R&D Offices to act more bureaucratically. R&D Offices might only accept an application once everything is in place, in order to speed up their turn-around times. 'Tracking' or 'audit of time taken' will also add more work to the approvals process for R&D Offices • When does the clock start? • There needs to be a nationally agreed list of core documents (e.g. for R&D approval) and criteria for what is a valid submission • When is the baton with the applicant and when is it with the approving organisation? 	<p>The NIHR IS team is working closely with Ian Goodall and the Central Sign-Off unit (CSOU) to ensure that systems are in place to support central sign-off from April 2008.</p> <p>The processes associated with central sign-off will defined and documented by the CSOU.</p> <p>Agreement on what is required for each and every type of trial is a key part of the design requirement for the R&DMIS and these do need to be agreed nationally and expressed through the wizards proposed for the R&DMIS.</p> <p>The location of the baton at each stage of the process should be with the organisation that has the next action in each case. What this actually means in practice will be defined as part of the R&DMIS design.</p>