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**VRIC: Virtual Research Integration Collaboration: A VRE aimed at
creating a framework to manage the research life cycles of basic
science and clinical research**

JISC Final Report

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Executive Summary

Translational research aims to provide a transition between basic science and clinical research trials in a streamlined process. Within a hospital context, this would be represented by a medical student conducting an investigation that does not require patients involvement and evolving it into a full clinical trial study using the basic science project as platform. The difficulties to achieve such goal are multiple, one of which being the effort required to preserve the processes and documentation regarding a study, in an environment that allows for materials to be re-used and re-purposed. In addition, the need to maintain a database of those people collaborating in multiple studies simultaneously at times, and maintain a record of the roles played in a particular study proves a challenging task for hospital organisation and medical researchers.

The aim of the project is to build a framework for the integration of basic science and clinical research to manage research lifecycles and allow for integration of scientific approaches throughout these lifecycles into the everyday work practice of the consortia that manage translational clinical research at the Royal National Orthopaedic Hospital (RNOH). In order to meet those aims, the user community participates as co-designers of the virtual framework providing input in relation to the inherent characteristics of medical research. In addition, they guide the process of meeting particular Ethical requirements which arise from developing a VRE in which researchers collaborate to handle medical data from multiple sites and who are governed by legal requirements from different countries and institutions.

The VRE integrates both with the RNOH institutional systems, research life cycle, and with the national systems such as the National Health Service (NHS).

The VRE has been successful in meeting the initial project objectives by having several people managing their trials and collaborating through it. There is a case of a trial that portrays the typical case of transitional research, as what started as a basic science study which was awarded with a recognition was continued into a full clinical trial involving patients. A recent trial involving over one hundred participants who took part of different experiments in which EMG data was collected, further exemplifies the uses that may be given to the VRE.

The overall methodological approach was that of co-design and co-deployment. For that reason, we engaged in an iterative cycle where problems typical of the RNOH were firstly acknowledged, followed by an exploration and definition of potential solutions, an implementation of the suggestions and finally an evaluation of the impact of the solutions on the participants work practices imp. Results of the evaluation were then feedbacked onto the system to initiate another co-design iteration, iteratively until the end of the development stage of the project.

The code and technical documentation from the project is available to other HEIs in the UK, so that it can be used either directly or as an example of how to build and expand the present VRE.

VRE was successful and taken positively by the end-user community. Governance proved to be a challenging module to develop since there is a need to oversee the research process but at the same time, whilst ensuring the continuity of the research process. Finding the balance is the challenge that hospital institutions R&D

Managers and medical staff seek. Transferring such balance into the VRE provided an important learning opportunity for the project team. For this reason, achieving positive results in how governance was implemented in the VRE is one of the strong points of the system.

For the research and teaching aspect of the project a major finding was the interest that end-users showed towards the development of the VRE. A tool that solves their needs in ways that address their needs facilitates the transition between paper-based trial documentation to a fully integrated VRE solution. On the technical side, the challenges of integrating disparate components using different programming languages and running on different operating systems platforms proved challenging yet rewarding from the developers' perspective.

In conclusion, the VRE has been successful up to this point. However, it is also in a state where it can grow to address the needs of other communities. Almost certainly, the input that other end-user communities may bring to the VRE will enhance its functionality and flexibility to become a generic tool for the creation, monitoring, reporting and dissemination of research studies in the medical field.

Background

It was our aim to provide a set of services at RNOH that would cover the four main areas of the research cycle, namely: the monitoring and governance of trials (experiment research administration); the trial protocols (experiment workflows); the publishing, dissemination and discussion on the results of trials in a repository; and the discovery of information from the repository and other resources.

In this abstracted model, the research lifecycle has been split into four main research activities. In each of these activities the different issues and stakeholders are addressed. The wider community nationally is represented by the Musculoskeletal network of Greater London, NHS, e-science, Surgical and VRE communities. It is through the Musculoskeletal network of Greater London that we will be able to co-ordinate knowledge and demonstrations to advise the community and for continuity. This project will impact on the wider academic community in the UK, initially through dissemination via organisations such as BriteNet (Tissue Engineering), The British Orthopaedic Association, British Orthopaedic Research Society, and the British Elbow and Shoulder Society as the groups tied into the consortia development.

Aims and Objectives

The aims set at the beginning of the project have remained. These are:

- To provide a set of services at RNOH to cover the four main areas of the research cycle, namely: the monitoring and governance of trials (experiment research administration); the trial protocols (experiment workflows); the publishing, dissemination and discussion on the results of trials in a repository; and the discovery of information from the repository and other resources changed during the project.
- To involve the user community in the co-design and co-deployment of the tools, in particular the front end of the work bench
- To explore the inter-operability issues raised from moving data between the VRE, the hospital systems (NHS) and the institutional systems involved in the project.

Methodology

The overall approach was that of co-design, between Orthopaedic Surgeons, R&D directors and researchers from the computer science. We had agreed the aims of the project but details to operate those aims were shaped by interaction with our research community.

One of the major challenges of adopting a co-design approach is to ensure that the project maintains a development plan that meets its original aims whilst still satisfying the research community expectations and addresses requirements that arise throughout the duration of the project. In order to support the co-development process, we maintained continuous contact with the user community and organised demonstration meetings after major upgrading and features release of the system. Furthermore, the computer science community were continuously advised on essential features of the VRE by a member of the Orthopaedic Surgeons community. This helped the computer scientists to prioritise the work that would give the VRE the greatest impact in the project lifecycle.

The initial phase involved a front-end analysis where requirements gathering and initial design took place. In order to accomplish the tasks relevant to this phase, the computer science formed a team with RNOH and an initial blueprint design was produced informed by a literature review and end-user interviews. To aid the understanding of how the system would be used, we outlined a typical 'research cycle' that included the practice of a clinical specialist in orthopaedics (who may also be a Higher surgical trainee) and a basic scientist. The purpose of this task was to identify time essential information provision and interaction with pervasive technologies.

From the initial analysis, the computer scientists built the VRE infrastructure, discussing development issues with the team of the myExperiment project. This was an iterative process supported by discussions of progress and results that took place at weekly meetings with the project team. The results of these were distilled into a system that satisfied initial as well as on-going requirements.

Reflecting on the initial list of requirements from the research community, it is satisfactory to confirm that the project has been able to meet all of them and in some cases, such as the trials collecting patient data from GP surgeries which required the use of iPads, even exceeded original expectations.

All members of the project team participated in the VRIC dissemination effort by recruiting national and international researchers to use the VRE, presenting the project in various meetings and seminars and providing end-users community with the support required to expand the use of the features in the system.

Implementation

The project was led by the School of Electronics and Computer Science (ECS) at the University of Southampton in partnership with the RNOH. The methodological approach adopted was that of co-design and co-deployment through which "designers cooperate with other experts and with [...] users and stakeholders and engage in processes of co-design, rather than doing the design work alone and in isolation" (Steen, 2009).

Progress was monitored in weekly meetings, from which minutes were kept. This effort ran in parallel to the continuous communication that took place between the ECS and the RNOH communities. Furthermore, the project team was always willing to have impromptu face to face as well as virtual meetings (with the RNOH) that were seen as required when a technical problem had been identified or feedback from the end-user community was received.

Each major release of the system was delivered in face-to-face sessions that took place in the RNOH. The reason for this was to give the computer scientist team members a clear idea of the work environment of the user community and most importantly, provide rich insight of the time constraint and work pressure that this

particular community face on a daily basis. For the VRE to be successful, it had to address those issues and provide tools that would facilitate the work practices of the community involved.

User case studies were built considering the profile of all users involved: Surgeons, Supervisors for MSc students, R&D Managers. The VRE followed different needs of each user-profile and created a flexible system that gives the R&D Managers the possibility of managing trials without hindering the progress of the research cycle.

Interesting practical lessons learned throughout the technical development of the project where the issue of compatibility with the software technologies exploited in the project, namely MyExperiment, ExtJS, IIS, Apache, Javascript and Python. It was a requirement from the end user community that the system run on Internet Explorer so all system features would be tested against this platform. It was a challenge to solve the technical problems that arose when attempting to make IE run the VRE without errors. This particular issue is also a successful story to tell as the development team was able to solve each of the problems detected when working with the IE platform.

The project was evaluated by the Software Sustainability Institute (SSI), feedback from the SSI has been undertaken to ensure that the project is sustainable and the code reusable by other HEI and stakeholders.

Outputs and Results

VRIC is available at <https://myvric.ecs.soton.ac.uk/>

The site allows researchers to create trials and document the research life cycle from inception to reporting stage.

There are a number of trials in the site ranging from those running within the RNOH and those in which collaboration with international communities have been established. For each of the trials, researchers are able to create a repository of documents relevant to the study, collect data through forms, create a team of collaborators (all the roles that the participants can have) and generate reports. Trials are stored in individual database structures that allow for a flexible handling of the data.

One major advantage of adopting a co-design strategy for development is the valuable input from the people that will ultimately be using the technology or system being developed. In VRIC, contributions from the end-user community at RNOH made evident the need to develop the VRIC's interface for deployment in touch screen devices. As a result, a web-interface to conduct a trial in clinics using the iPad as the touch screen data collection device was developed, the trial and corresponding forms were created in VRIC to store the data captured on the iPad and this sub-project is now part of a clinical trial to gather information on elderly patients to assess their risk of developing osteoporosis. This effort involved the work of clinicians, staff and patients on the medical side, and the ECS team in the computer science side and is evidence of a successful outcome originated from a co-design and co-deployment methodological strategy.

A trial involving over a hundred participants that generated large data files was managed through the VRE. Data captured in a location in London was stored in VRIC and analysis was conducted with researchers based in Canada. This type of collaboration was enabled via the VRE trial and collaboration features.

Outcomes

Overall, the project has been a success. It met the aims and objectives by bringing together research lifecycles, communities and Web 2.0 tools through a VRE that is being actively used by surgeons, researchers and students.

The VRE allows the research community and directors at the RNOH to:

- Monitor and manage governance of trials (experiment research administration);
- Monitor, document share and collaborate with the trial protocols (experiment workflows);
- Organise the publishing, dissemination and discussion on the results of trials in a repository; and
- Discovery of information from the repository and other resources

Work practices of people involved were changed in different ways as reported by the end-user community in a feedback questionnaire applied in late September 2010. The VRE gave users a better sense of self-control over their learning and working space and their perception is that they were able to work faster when using the system. The questionnaire allowed us to also identify areas of improvement for the VRE, such as the importance of providing technical support to improve users' confidence in the use of technology in the documentation of a research trial.

This work has the potential to offer benefits to other medical communities, as it is the potential case of a community of Neurosurgeons in the UK who are in the process of building a network of researchers and using a web application as collaboration environment.

A review of VRIC features at present has generated uptake interest in Canada which could lead to further development of the VRE.

Conclusions

The aims established at the beginning of the project were met in the VRE delivered. The approach of co-design and co-deployment proved to be highly rewarding for the user community and the computer science team.

Implications

The main areas of development that can take this work further revolve around expanding and enhancing tools within the VRE. A strong technical design based on open standards facilitates the development of tools that enhance the site functionality. This proposition opens up endless opportunities to the computer science community with regards to development and dissemination of the project.

The VRE and associated tools offer a good working environment to the medical professionals, however, it must be recognised that even if all efforts were made to try and create a flexible platform that could meet the requirements of different institutions, the trial templates in place do not cover all possible research cycle scenarios. The technical implications for this issue present the need to modify the VRE study templates to accommodate a dynamic research model, allowing researchers to create the research cycle that best suits their needs.

In addition, data collection features in the VRE are targeted to Orthopaedic surgeons and the trials currently existing in VRIC. Implications for other professionals in the medical field are that of development time to create the data collection structures to suit particular trial needs. In order to enhance the system flexibility, we

suggest the development of a form creation module within the VRE which will give researchers autonomy to capture data through forms that suit specific requirements of any study.

An additional implication identified through the multiple consultation meetings conducted with end-users relates to collaboration of researchers based in multiple institutions to analyse data from a trial. At present, the VRE provides features to oversee governance of a trial which complies to the regulation of the RNOH. Governance has been developed in ways that allow rules to be modified so that R&D officers from different institutions may set up different policies for different trials. Data analysis however is still dependant on the researcher's initiative to share data and establish analysis strategies and results. An analysis module for the VRE would also enhance the collaboration features of the site if researchers were given tools to set up among other things data sharing policies or statistical analysis tools.

The success of the VRE reached at present is only opening a great number of possibilities for the professionals in the field of medicine in multiple areas. It must be recognised that future work is required in order to develop the tools to provide as much flexibility as required by the medical professionals. However we have established the principles of a strong VRE which may be enhanced following the co-design approach adopted in the project working with other end-user communities.

Recommendations

One of the most relevant lessons learned in the project regarding teaching is the time that must be devoted to provide training in technical aspects of the tools being developed for the community of end-users. The co-design and co-implementation approach ensures users participation in the creation of the VRE, however, the approach does not guarantee that people will have the confidence to use the technology. It is important to plan hands-on training while users perform daily activities in their work place. That type of training is likely to show how technology may be integrated into users' work practices.

References

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