

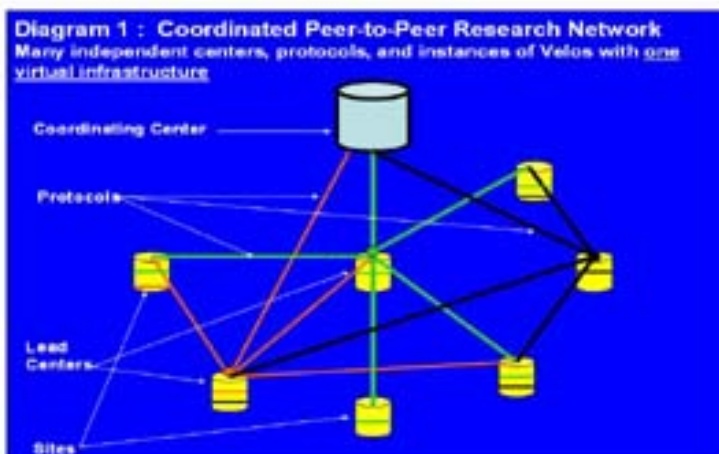
Scalable, Federated, caBIG Compatible Clinical Trials--Technology in Use

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Background

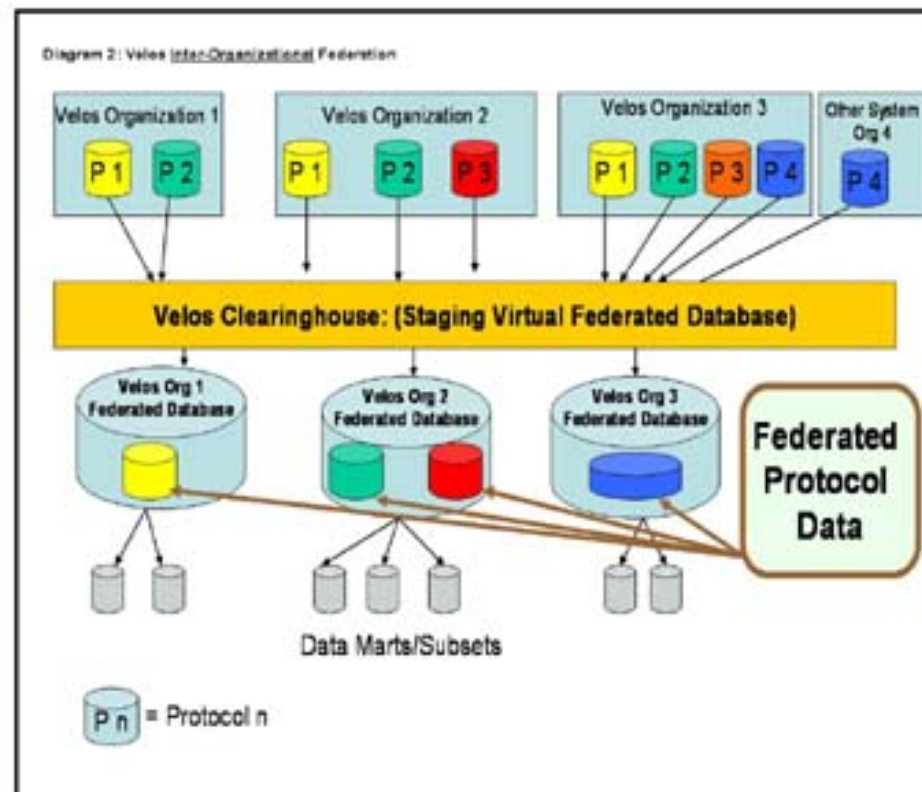
Networks of investigators in one specialty are a significant asset for the conduct of clinical trials in one disease. Such networks are usually assembled ad-hoc on a per-trial basis. Trial sponsors often provide technology to support the trial. This leaves investigators with multiple technologies, multiple end databases, and duplication (multiplication) of data entry to support sponsor, institutional, departmental, and regulatory reporting needs. The PCCTC (Prostate Cancer Clinical Trials Consortium) has worked with Velos eResearch on an ambitious network architecture for clinical trials to support research in a network for prostate cancer trials across multiple elite centers.



The Needs

In such a network, the following needs were identified:

- Singularity of trial infrastructure with separate physical instances and databases
- Central protocol design, authoring, and propagation to participating centers
- Central authoring of CRFs (case report forms), and propagation to sites
- Ability to support trial-specific lead and participating sites within the network, with data accrual to lead site database
- Protocol specific ability to centralize or decentralize control of patient registration
- Process appropriate custom messaging
- Semantic harmonization
- Local integration and interfaces to lab, ADT, etc.
- Openness: ability for investigators to simultaneously manage non-network trials on the same infrastructure



Technology in the Network

An architecture and topology were created to support:

1. **Network Scalability:** The network is designed to allow new centers and sites to join it seamlessly. These additions have no impact on current members, their systems and process, or their hardware.
2. **Instance Scalability:** Any individual site can scale locally to a desired number of users, and introduce sub-networks or other participating sites, without impact on the prime network. This allows the creation of a **Network of Networks**, now underway in several instances.
3. **Federation:** The network instances are federated to allow protocol, schedule/calendar, and form (e.g. CRF) exchange through federation and propagation controls. Equally, study data follows the path of reverse propagation in this federated environment, from the participating sites to the lead center or the coordinating center.
4. **Compliance:** The uniform architecture and architectural protection from localization or customization mean the entire network is caBIG compliant at the same level as any single instance of the infrastructure system (Velos eResearch).

Results

1. The network has been instantiated with site specific infrastructure instances at 8 major centers in the United States. Applications from several centers in the US and abroad are under consideration by the PCCTC.
2. Trials have been conducted "in-network" for over two years, including patient lab and CRF management.
3. Twenty studies are scheduled for production over the next year.
4. Over 300 users are part of the network, in institutions with a total of 2,000-plus Velos users.
5. Semantics for these sites have been homogenized.
6. The network has uniquely amalgamated data from multi-center internal automated interfaces and CRFs to the lead center, and from there to the NCI's CDUS. It is expected that this mechanism will feed the caBIG grid in the future [<link>](#) [<link>](#).

Discussion and Comment

Challenges--Initial challenges were systems related:

- Unique patient ID management in a federated world;
- Change control mechanisms, audit, and security;
- Federation.

Later challenges were:

- Disagreements on semantics
- Clarification of command and control.

Expected future action :

- Live links into caBIG grid

A model of a unique federated, scalable, and caBIG compliant network is presented. The model has overcome security, architecture, complexity, and process related concerns and issues, and has been in production for over two years. Explaining the complex architecture, network, and dataflow to the community continues to be a challenge. The network is expanding.

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