UC TrialQuest: 2016 Sautter Award Application

About UC BRAID

UC BRAID (Biomedical Research Acceleration, Integration & Development) is a consortium of the 5 UC Health campuses dedicated to accelerating biomedical research and developing efficient processes that foster synergies across participating campuses. We strive to catalyze research aimed at improving health across California and around the world. UC BRAID has quickly established a well-connected network of multi-campus leaders, faculty, administrators, and UC Office of the President partners that is a powerful driver to advance and improve research infrastructure. UC BRAID has become a major resource for identifying needs, coordinating multi-campus expertise, and enabling partnerships.

Project Title:	UC TrialQuest: Sharing Clinical Trial Data Across UC
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UC TrialQuest Overview

Prior to UC TrialQuest's deployment in July 2014, there was no efficient means of identifying clinical trials, open or pending, in real time across the 5 University of California (UC) Health campuses. This lack of information created a significant obstacle for a number of groups involved in the research process, notably IRB staff, contract negotiators, and potentially researchers themselves to rapidly initiate multi-campus research projects and clinical trials. To address this gap, UC BRAID built a clinical trials search tool, UC TrialQuest, in conjunction with UC San Francisco's CTSI Research Technology team. This web-based database contains weekly updates on clinical trials in the process of, or having received, IRB approval at the 5 UC Health campuses over the last 3 years.

Developing this tool required close collaboration between numerous teams across the UC Health campuses, made possible through UC BRAID, and is a demonstration of the innovation possible at UC despite limited resources.

TrialQuest was initially targeted toward IRB staff and campus contracting teams, reducing redundant effort for common research administration processes and potentially expediting activation of clinical trials. For example, IRBs use the tool to screen incoming IRB applications. If a given study has already received IRB approval at another campus, IRB intake analysts can pursue IRB reliance, or Single-IRB mechanisms, also established through UC BRAID, where a single IRB review can be used by any number of other UC campuses.

Likewise, contracting teams use the tool to see if another campus has negotiated with industry sponsors for a clinical trial. Knowledge of trials at other sites can accelerate the negotiation process and gives negotiators an opportunity to share contract terms.

While similar in function to UC TrialQuest, ClinicalTrials.gov suffers from a number of shortcomings, including inaccurate, incomplete, or out-of-date records and therefore does not fully meet the needs of our research stakeholders. The development of UC TrialQuest was partly in response to this need, and leverages the strength and superiority of weekly IRB data.

With growing use and awareness of the tool, we have received numerous requests for feature enhancements, including expansion of the targeted user base to include UC researchers. Building on our initial success, we are nearing release of the next major version of TrialQuest, which includes features aimed at both researchers and research administrators alike.

Collaboration is the Foundation of TrialQuest

Realizing that TrialQuest requires access to IRB data, we started by bringing in the IRB Directors to garner support for the tool and to increase their level of comfort in sharing IRB data. With their buy-in, we turned to campus technology teams to help design the weekly reports that populate the database. TrialQuest would not be possible without this spirit of collaboration across UC.

Developing the Technology

Development of TrialQuest was less than 3 months from concept to deployment, making good use of the modest budget available. UC BRAID credits the strong campus partnerships that made this rapid development possible. With the extensive UC BRAID collaborative relationships in place, developing the technology was a smooth and efficient process.

Each of the 5 campuses manages IRB data using different and unlinked systems, with no common ontology. Given the wide variety of data export formats in those systems, we decided to accept data in whatever formats were available, developing software to normalize a variety of container spreadsheet data formats to a single canonical representation. We then mapped each university's data to the seven fields TrialQuest uses for search results.

After mapping data to a common metadata schema, we developed a web interface offering the ease-of-use available with industry-leading search engines. We used the DataTables open source JavaScript library to develop a single search box application where users' type-ahead searches would run across all fields. Type-ahead searches run in real time, allowing users to easily understand the results and refine searches as needed.

We built TrialQuest with a modular underlying structure that will make it easy to add other UC campuses to the tool, or to share the tool itself with other institutions. Hooks for other groups to download data directly from TrialQuest are also on our roadmap.

Major Enhancements in TrialQuest 2.0

Gene and drug synonym support: This feature significantly increases utility for researchers and groups such as tumor boards. For example, HER2 and CD340 represent the same gene, so searching for one also returns studies containing the other. This approach also supports generic versus brand-name drugs (e.g., avastin = bevacizumab). The HUGO gene database and drug information from the FDA provide the basis for this feature.

Single Sign-On: TrialQuest is registered with InCommon Federation to allow single sign-on for all UC campuses while protecting potentially sensitive information. This also establishes a foundation for extending access to institutions outside the UC system should such a collaboration develop.

"Click to Rely" on IRB approval at another campus: The national landscape for human subjects protection is quickly shifting toward Single-IRB review, including an upcoming federal mandate. Researchers looking to start a clinical trial can search TrialQuest for IRB-approved trials, and then avoid a redundant IRB application and review by clicking "Rely" to utilize Single-IRB. This saves time and resources for researchers, study teams, and IRB staff and committees. (Note: this feature will be turned off while campus IRBs prepare to support an increase in IRB reliances.)

"Best Match" links to Clinicaltrials.gov: Only two campus IRBs collect clinicaltrials.gov information for studies, which TrialQuest uses to link studies to that site for additional information. To enable this functionality for the other campuses, TrialQuest compares IRB records with clinicaltrials.gov to suggest the most likely match between a study at UC and the corresponding record at clinicaltrials.gov.

Measuring Success

To date, TrialQuest has mitigated over 40 duplicative IRB reviews. However, this is only a fraction of the total number of duplicative reviews each year. Analysis of TrialQuest records indicates approximately 150 such reviews annually, and the number is increasing. As IRBs begin expanding their IRB reliance programs, TrialQuest will be critical in minimizing redundant reviews. For reference, eliminating a single redundant review saves UC thousands of dollars in addition to other resources. With a very conservative real-world estimate of $4,000 for each IRB review, this would equate to over $600k saved annually.

Reducing redundant IRB reviews is only part of the picture. With the enhancements in version 2.0 and our efforts to promote TrialQuest to a wider audience, we anticipate a sizable increase in utilization. Web analytics will help us track usage and see which campuses take greatest advantage of the tool and where we need to increase our outreach efforts. A customer feedback link provides users a means to request assistance or suggest features, which helps us understand what works and what needs improvement in future versions.

Ultimately, we hope that researchers will add TrialQuest to their arsenal of tools to help patients find clinical trials from which they may benefit, which will be the most important measure of success.

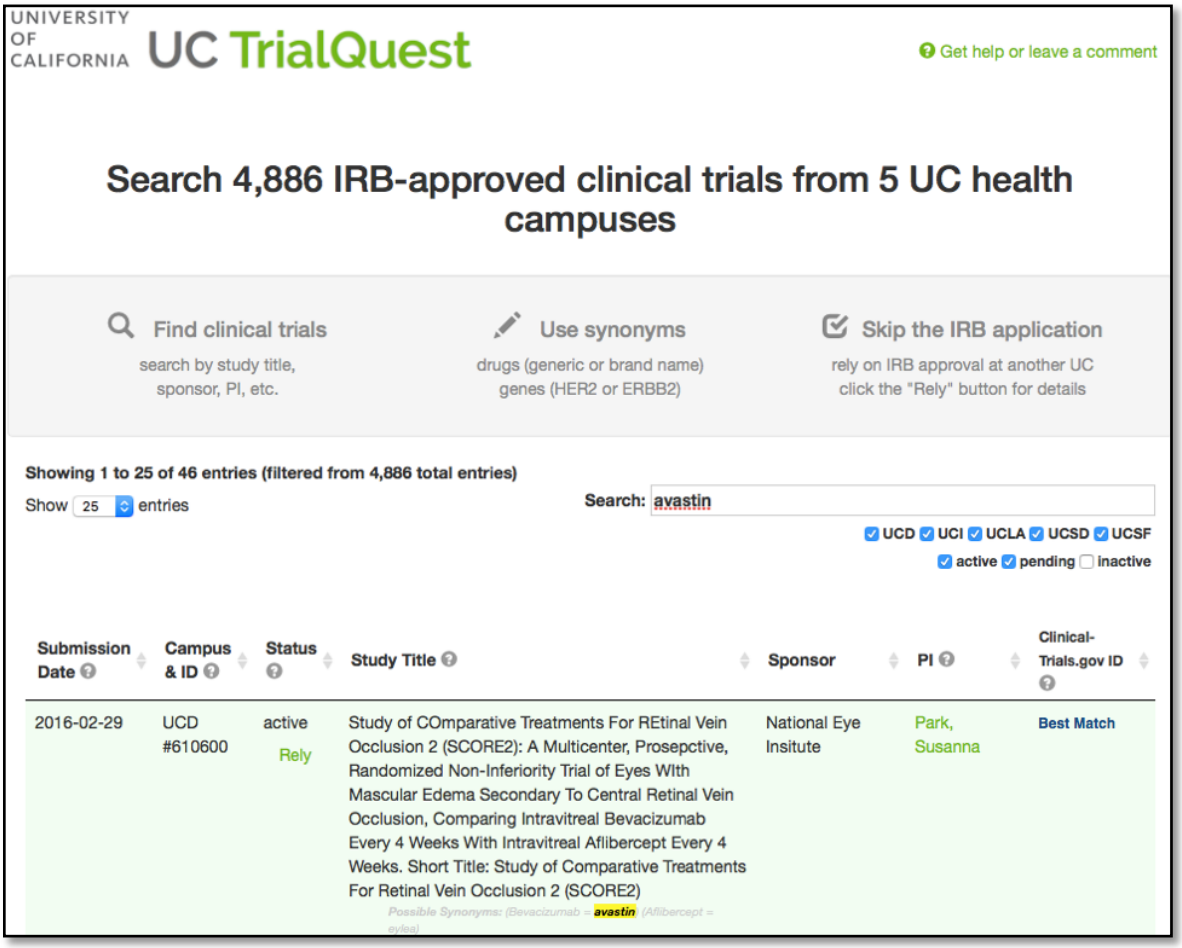
Looking to the Future

UC TrialQuest is a simple tool with a multitude of uses. With an increasing number of users, we plan to leverage IRB data and make the tool even more valuable for researchers and research administrators.

UC BRAID has laid the foundation for sharing information such as these IRB-approved clinical trials. This platform of open collaboration can help spawn other new and highly-integrated uses of data across UC. We invite inspired and creative teams to reach out to us for potential collaborations or data sharing.

TrialQuest Screenshots

Full TrialQuest Tool



Synonym Support—Searching for gene CD340 also returns HER2 matches