UC BRAID Reliance Services (UCRS)

Eric Mah, Nate Buscher, Courtney McFall, Rachael Sak

October 16, 2015
Contributors

• UCRS Advisory Group – Karen Allen, Lisa Denney, Cindy Gates, Kip Kantelo, Anthony Magit, Christopher Ryan

• IRB Reliance Coordinators

• UCOP – Jeff Hall, Dragana Nikolajevic, Agnes Balla, Patrick Rogers, Hillary Kalay

• UCSF CTSI – Anirvan Chatterjee, Leslie Yuan: UC TrialQuest prototype
UCRS Overview

• UCRS reduces duplicative IRB reviews for clinical trials, speeds trial activation, and minimizes PI/study team effort

• UCRS is poised to respond to a shifting national IRB Reliance landscape:
  – NCATS IRBRely Project
  – NIH Proposed Rule of single-IRB review
  – HHS Notice of Proposed Rule Making (NPRM)
UCRS Activities & Achievements

**National Recognition**
- UCRS showcased at upcoming PRIM&R conference
- TrialQuest featured at AMIA last March

**Expansion & Efficiency**
- 26 reliances to date vs. 5 last year
- Reliance approval time= 11 days and decreasing
- More types of studies (e.g., NIH-funded)

**Partnerships**
- Formed IRB Advisory Group
- TrialQuest & UCOP
- ACTG piloting trial through UCRS
- Exploring cancer center collaborations

---

UC BRAID
innovation•collaboration•acceleration
Demand for Reliances Increasing

• Over 350 duplicative IRB reviews in past 3 years
• IRBs, Cancer Centers, and disease networks all face increasing # of protocols
• Sponsors seek multisite trials with minimal delays
• Upcoming NIH requirement of single-IRB review
Progress & Opportunities

- Increase UCRS throughput and capacity with technology tool (early-Dec. deployment)
- Work with campuses to generate revenue
- Develop long-term plan to staff UCRS and create a sustainable service offering
- Make TrialQuest available to research teams, enabling earlier identification of reliance opportunities
### Search 4,628 clinical trials from 5 UC health campuses

**by UC BRAID • CTSI at UCSF • UC Office of the President**

![How to use this (1 min video) 🎥](#)  [Get help or leave a comment](#)

---

**Show** 10 entries

Showing 1 to 10 of 3,795 entries (filtered from 4,628 total entries)

**Search**: e.g. lapatinib, mcdonald, novartis, ucsf novartis

- [ ] active
- [ ] pending
- [ ] pre-submission
- [ ] Inactive
- [ ] UCD
- [ ] UCI
- [ ] UCLA
- [ ] UCSD
- [ ] UCSF

---

<table>
<thead>
<tr>
<th>Submission Date</th>
<th>Campus &amp; ID</th>
<th>Status</th>
<th>Study Title</th>
<th>Sponsor</th>
<th>PI</th>
<th>Clinical-Trials.gov ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015-09-15</td>
<td>UCSF #15-17625</td>
<td>pending</td>
<td>CC# 15756: A Phase II Clinical Trial of Pembrolizumab (MK-3475) as Monotherapy for Metastatic Triple-Negative Breast Cancer (mTNBC) (KEYNOTE-066)</td>
<td>Merck Sharp &amp; Dohme Corp</td>
<td>Rugo, Hope</td>
<td></td>
</tr>
<tr>
<td>2015-09-15</td>
<td>UCSF #15-17527</td>
<td>pending</td>
<td>Randomized Trial of a Best-Practice Alert in the Electronic Medical Record to Reduce Unnecessary Telemetry Monitoring</td>
<td>None</td>
<td>Najafi, Nader</td>
<td>02529176</td>
</tr>
<tr>
<td>2015-09-14</td>
<td>UCI #2015-2355</td>
<td>pending</td>
<td>Monitoring and Predicting Breast Cancer Neoadjuvant Chemotherapy Response Using Diffuse Optical Spectroscopic Imaging in a Multi-Center Setting</td>
<td>Tromberg, Bruce</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>