Project Completion Report

ESTR Product Path Project

April 2016
Presentation at the PRC Monthly Meeting
Project Completion Summary - ESTR Product Path Project

Summary Metrics

- **Budget**: 1% under (approximate)
  - Green = less than 10%, Yellow = between 10% and 20%, Red = more than 20%
- **Schedule**: 0 months late
  - Project tasks were shifted due to technical issues and business needs, but the whole project will be completed on schedule.
- **Total Value Achieved**: Total value achieved is a qualitative assessment and cannot be evaluated as this type of percentage.
  - Green = 90% Yellow = between 80% and 90%, Red = less than 80%
- **Open Serious Defects**: 1
  - Green = 0 Yellow = between 1 and 3 Red = more than 3

Award: $120,456
Spent: $120,456 projected
$100,000 actual YTD

Start: 07/2015
End: 06/2016

Major Benefits Achieved

- Using the vendor-supported version of the system, allowing for easier regular upgrades
- Increased ease of use for Faculty and IRB staff, that will continue to improve over time
- Reduction in time and effort to assess and develop Harvard specific updates
- Established an ongoing plan for system updates with reduced Harvard-based planning and development

Key Success Factors

- Documented Harvard-specific configurations that will be re-implemented at each upgrade
- Accepted strategy for biannual upgrades provided by the vendor
- Updated training materials for users

Areas for Improvement

- Additional enhancement of in-system reporting capability for Harvard-specific on-demand reports
- With vendor-provided resources, streamline regression and user acceptance testing
**Vision* - ESTR Product Path Project**

**The Vision for ESTR Product Path**

*Provide robust, enduring, and cost effective development support for the University-wide, Electronic Submission Tracking and Reporting (ESTR) system for Institutional Review Boards (IRBs).*

<table>
<thead>
<tr>
<th><strong>Objectives</strong></th>
<th><strong>Guiding Principles</strong></th>
<th><strong>Key Performance Indicators</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Update the ESTR system to allow for application of vendor-developed releases with minimal re-design</td>
<td>1. Commitment to open, clear, and timely communication between stakeholders</td>
<td>1. Creation of a Harvard Configuration Patch to be applied with each release</td>
</tr>
<tr>
<td>2. Leverage cost-saving opportunities offered by the vendor</td>
<td>2. Promote collaboration and engagement across stakeholder groups</td>
<td>2. Incremental upgrade to the current vendor-release</td>
</tr>
<tr>
<td>3. Enrich level of engagement with the Huron community, to influence changes</td>
<td>3. Foster positive system use and trust by reducing the need for workarounds and maximizing ease of use</td>
<td>3. Updated documentation, training, and user feedback materials</td>
</tr>
<tr>
<td>4. Enhance stability and capability to maintain compliance over the lifespan of the system</td>
<td>4. Scale down customizations to ensure alignment with the upgrade path</td>
<td>4. Upgrades delivered in a timely manner and at an acceptable cost</td>
</tr>
<tr>
<td>5. Increase opportunities to address more sophisticated changing business needs</td>
<td>5. Minimize disruption to the user community</td>
<td>5. Redesigned long term support resource and upgrade plan</td>
</tr>
<tr>
<td></td>
<td>6. Design to ensure integration with other Harvard systems</td>
<td></td>
</tr>
</tbody>
</table>

*The project vision remains unchanged from the original ITCRB Project submission.*
Vital Statistics

- Project Name: ESTR Product Path
- Project Manager: Alisa Jahns
- Functional Area: FAD-FSS Enterprise Research Administration
- Lead Sponsor: Ara Tahmassian (OVPR)
  Co-Sponsors: Pamela Caudill (HMS), Delia Wolf (HSPH)

### Timeline Planned and Actual

<table>
<thead>
<tr>
<th>Phase</th>
<th>Planned Start</th>
<th>Actual Start</th>
<th>Planned Finish</th>
<th>Actual Finish</th>
</tr>
</thead>
</table>

### Costs – Planned and Actual

<table>
<thead>
<tr>
<th>Phase</th>
<th>Total Approved</th>
<th>Budget</th>
<th>Actual</th>
<th>Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation</td>
<td>$120,456</td>
<td>$120,456</td>
<td>Expected: $120,456</td>
<td>$0 Anticipated on-budget</td>
</tr>
</tbody>
</table>

*ITCRB funding was for a one year implementation only, and there were no change requests.*
Project ROI*

*The projected ROI remains unchanged from the original ITCRB Project submission.

<table>
<thead>
<tr>
<th>ROI CALCULATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>COSTS</td>
</tr>
<tr>
<td>Total Project Cost</td>
</tr>
<tr>
<td>Annual Incremental Operating Cost</td>
</tr>
<tr>
<td>ESTIMATED ANNUAL VALUE</td>
</tr>
<tr>
<td>New Annual Revenue</td>
</tr>
<tr>
<td>Annual Savings</td>
</tr>
<tr>
<td># of FTEs affected</td>
</tr>
<tr>
<td>% of labor effort saved per year</td>
</tr>
<tr>
<td>Annual Efficiency Gain</td>
</tr>
<tr>
<td>TOTAL ANNUAL VALUE</td>
</tr>
</tbody>
</table>

CALCULATED ROI (Year 1) 31%

- Observed reduction in staff effort to prioritize, design, and test custom-created changes and create reports for operations analysis.
- The reduction of effort will gradually increase over time and can be better-assessed after the first year.
- The next regular update will include approximately 215 vendor-produced system updates (ranging in complexity), estimated at 200 development hours (or $42,000 of contracted development) at no additional cost to Harvard.
Objectives Realization

Problem or Opportunity Statement

The goals of ESTR are to:

• Maintain a University-wide, web-based technology platform, recognized by The Association for the Accreditation of Human Research Protection Programs (AAHRPP).
• Support a more robust, consistent, and streamlined tracking of human subjects protocols reviewed and approved by the IRB offices.
• Eliminate paper processes for protocol submissions, decreasing the administrative burden on faculty and staff.

Continuing to achieve these basic goals will become increasingly costly if care is not taken to realign the system to the Click® IRB product path.

Problem Resolved or Opportunity Realized

✓ Successfully transitioned to the vendor-supported application in October 2015 while maintaining key Harvard configurations.

✓ Engaging in an extended vendor-support contract to ensure stable cost and increased savings over time.
Benefits Realization

Anticipated Benefits

Leverage the changes identified by Huron and their client institutions, along with hundreds of hours of developer time devoted to each Click release. Key additional benefits of this include:

1. Greater assurance of compliance with federal regulations and AAHRPP accreditation requirements;
2. Increased usability over time, as the Click® IRB product matures; and
3. A system roadmap which extends beyond the next five years with reduced Harvard-based development.

Achieved Benefits

Each anticipated benefit has been achieved to some measure, but will be realized in the years following project closure.

- Reduced time to complete compliance and operations monitoring reports
- First six month assessment points to usability improvements
  - Types of help desk inquiries have changed, requiring less investigation and system correction
- Current roadmap documented for two releases per-year
Benefits Realization [continued]

Ongoing Benefits Tracking
Research Administration Systems team members and IRB leadership plan to complete annual system assessments. The following KPIs will be assessed:

- On-time successful application of Harvard configurations at each biannual upgrade
- Annual evaluation of services to cost for Click extended support contract
- Status and upkeep of documentation, training and user feedback materials

Other Benefits
Improved vendor-provided functionality has resulted in unexpected benefits:

- Reduced time from application creation to submission
- More Harvard-custom features were successfully retained than originally expected
Features and Requirements Delivery

Delivered Planned Features/Requirements

• Data migration from the current custom system was completed, with development to create space for Harvard-specific data
• Harvard configurations were designed, documented, and applied
• Specification, training, and other documentation was updated
• The long-term support plan is in place, with vendor-agreement pending

Planned Features/Requirements Not-yet Delivered

Based on the adjusted project plan the following features/requirements are not yet delivered, but remain on schedule for completion prior to project closure.

• Complete first regular Click® IRB upgrade [anticipated June 2016]
• Execute long term support plan with vendor [anticipated June 2016]

Significant Changes to Scope

The overall scope of the project remained unchanged throughout. However, key challenges associated with upgrade expanded the work required to complete the transition.

• The volume of data to migrate required more development than initially anticipated.
• Change management impact for upgrade led to:
  – Rescheduling the first regular upgrade to Q4 (rather than planned Q2) and
  – Revised release schedule from once quarterly to two times per year.
# Project Quality

<table>
<thead>
<tr>
<th>Product Defects/Bugs</th>
<th>Closed</th>
<th>Open</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>13</td>
<td>1</td>
</tr>
<tr>
<td>High</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Medium/Low</td>
<td>77</td>
<td>58*</td>
</tr>
</tbody>
</table>

*Open bugs/defect tickets represent the cumulative list of items reported before and during the project. These bugs/defects are either a result of the vendor delivered application issues or Harvard configurations.*

## Open Critical Defect Description

<table>
<thead>
<tr>
<th>Description</th>
<th>Owner</th>
<th>Date Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allow for document upload on Track Harvard Determinations activity. There is a workaround in place until the bug fix is completed.</td>
<td>Alisa Jahns</td>
<td>June 2016 upgrade</td>
</tr>
</tbody>
</table>
Transition

Ongoing Governance

- Lead Product Owner: Ara Tahmassian (OVPR)
  Co-Owners: Pamela Caudill (HMS) and Delia Wolf (HSPH)

- Ongoing governance: For defect correction and enhancement requests, governance maps to the project governance for review of enhancements and bug fixes.

Ongoing Support

- Service Owners: Sara Sclaroff (HUIT) and Simone Alpen (FSS)
- Support team/structure: Support maps to the structure for the project.
- Support team training/preparation: The project BSA is the ongoing support BSA. No additional training is required.
Transition [continued]

Communication and Engagement

What worked

• Use of Slack messenger and GoToMeeting helped connect the fully remote development and business-side teams.
• During the height of the project, weekly email status updates to the Sponsor team.
• Use of the Wiki as a central resource for team decisions and documentation.
• Creative use of the site banner and email signatures to broadcast coming changes to end-users.

What didn’t work

• Direct communication from the Point Person team to members of the Leads Team was insufficient during active stages of the project. Addressed with updated expectations in the operational transition.
• Attempting to use Slack for document management. Abandoned use of Slack to instead (successfully) use email, Wiki and Confluence for document sharing and version control.
Lessons Learned

Surprises
• Onboarding the vendor developers took longer than anticipated.
• Initial vendor assessment predicted development at 1/3 of the actual time needed.
• Non-System Policy/Process discussions occurred more often than anticipated.
• Preferred release frequency was reduced to two times per year, rather than four.

Best Practices
• Stable construct of the project team, with crossover between groups allowed for flexibility in keeping teams informed
• Prioritizing change management and the end user experience when making customization/configuration decisions supported more efficient transition to the upgraded system

Lessons Learned
• Anticipate and if possible, reduce concurrent tasks
• Plan extra time for testing
• Establish a business partner time-investment tracking tool