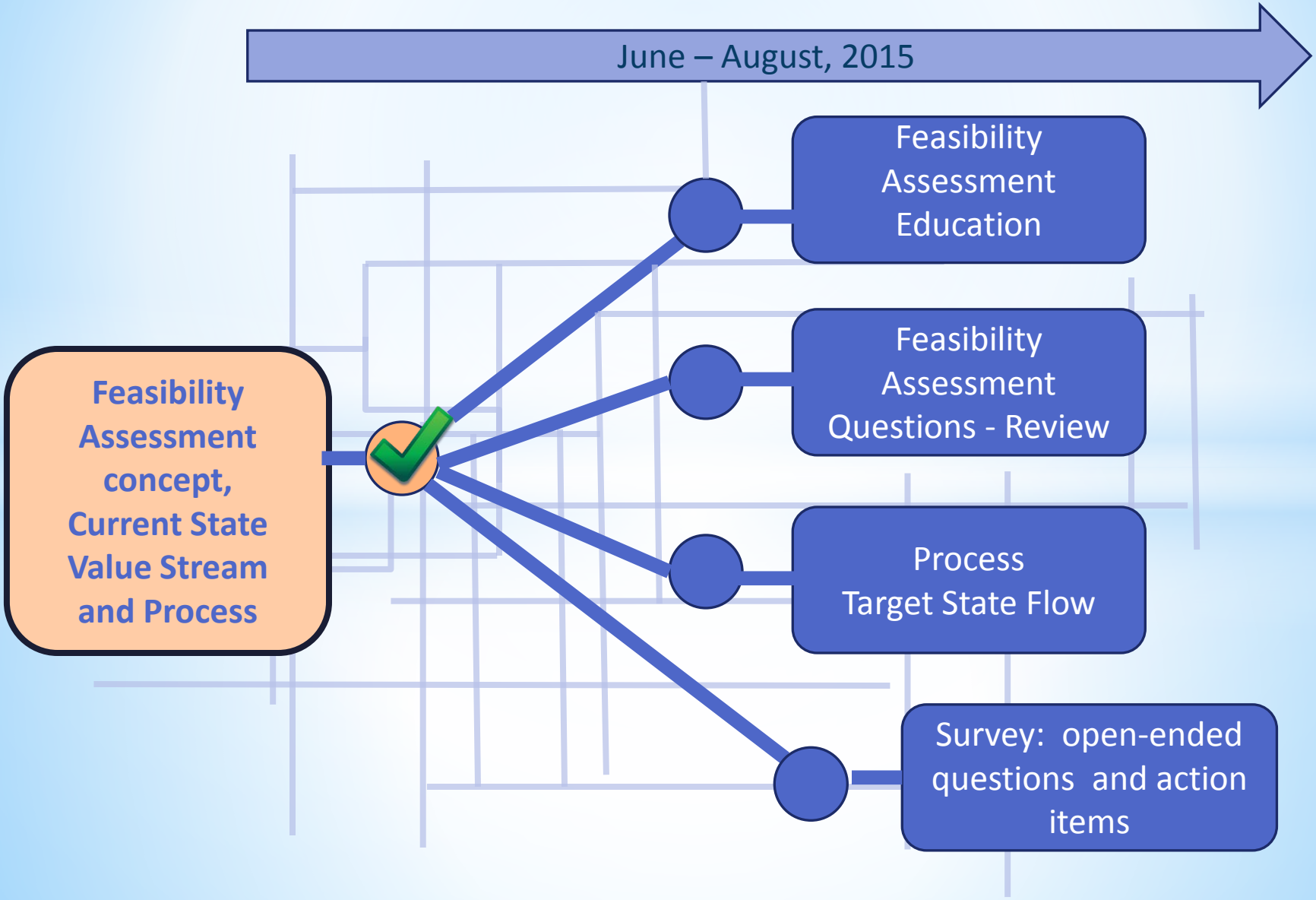
Clinical Research Improvement in Systems and Processes

August 6, 2015

The map of our journey - agenda



Why do Feasibility Assessment

Data from 2014-2015 has shown that up to 30% of studies at UVa are closed prior to completion
of which almost 20% had no subjects enrolled

Why do Feasibility Assessment

Study closed due to no funding, time, personnel to do the study

25% of Full Board studies do not enroll subjects

13% of Expedited studies do not enroll subjects

Last known enrollment report at the time of closure, FY14-15

Feasibility Assessment – Proposal

Creating standard and systematic approach to feasibility assessment in each Department/Center

Value to Principal Investigator and Department/Center:

- Awareness and education
- Preparation and integration with downstream
- Planning, prioritization, and informed commitment

Additional Institutional Value:

- Manage Work-In-Process

Feasibility Assessment items to consider

- Study general information
- Scientific review
- Subject/Patient needs and availability
- Enrollment (sponsor and internal)
- Sponsor consideration
- Faculty consideration
- Methodology/Operational considerations
- Budget consideration and cost analysis

May depend on the type of study and timing

Feasibility Assessment – timing

Start: Principal Investigator has a protocol from a sponsor or a protocol design

Prior to any study set-up activities

Feasibility Assessment – when requesting grant funding

Pre-Award

- ✓ Increase quality and likelihood of being funded
- ✓ Answer “should we do it”
- ✓ Facilitate planning earlier in the process (“how”, “can”)
- ? Time and support to do it well
- ? Not 1:1 relationship: grant proposal and study project
- ? Significant changes in the process

Post-Award

- ✓ Focused on the projects that are funded
- ✓ Value of “how to do it well” with the money received

Feasibility Assessment – proposed automated process, first phase:

Start: PI has protocol (sponsor) or protocol design

AND established funding source (Grant, Contract, Internal)

Process

- Principal Investigator/Study team completes Feasibility Assessment questions
- Principal Investigator/Study team submits the Feasibility Assessment to Departmental/Center Committee
- Departmental/Center Committee reviews and provides feedback, approval/rejection; Opportunity to see portfolio and prioritize

Feasibility Assessment – steps to review and finalize specification

- Advisory feedback (PI, Committee, Administration, Department Chair)
- Need to support – education and specific training for PI/Study team members, Department/Center Committee, Department/Center Administration
- Standardization
- “Comprehensive” and “easy”

Concept of target condition

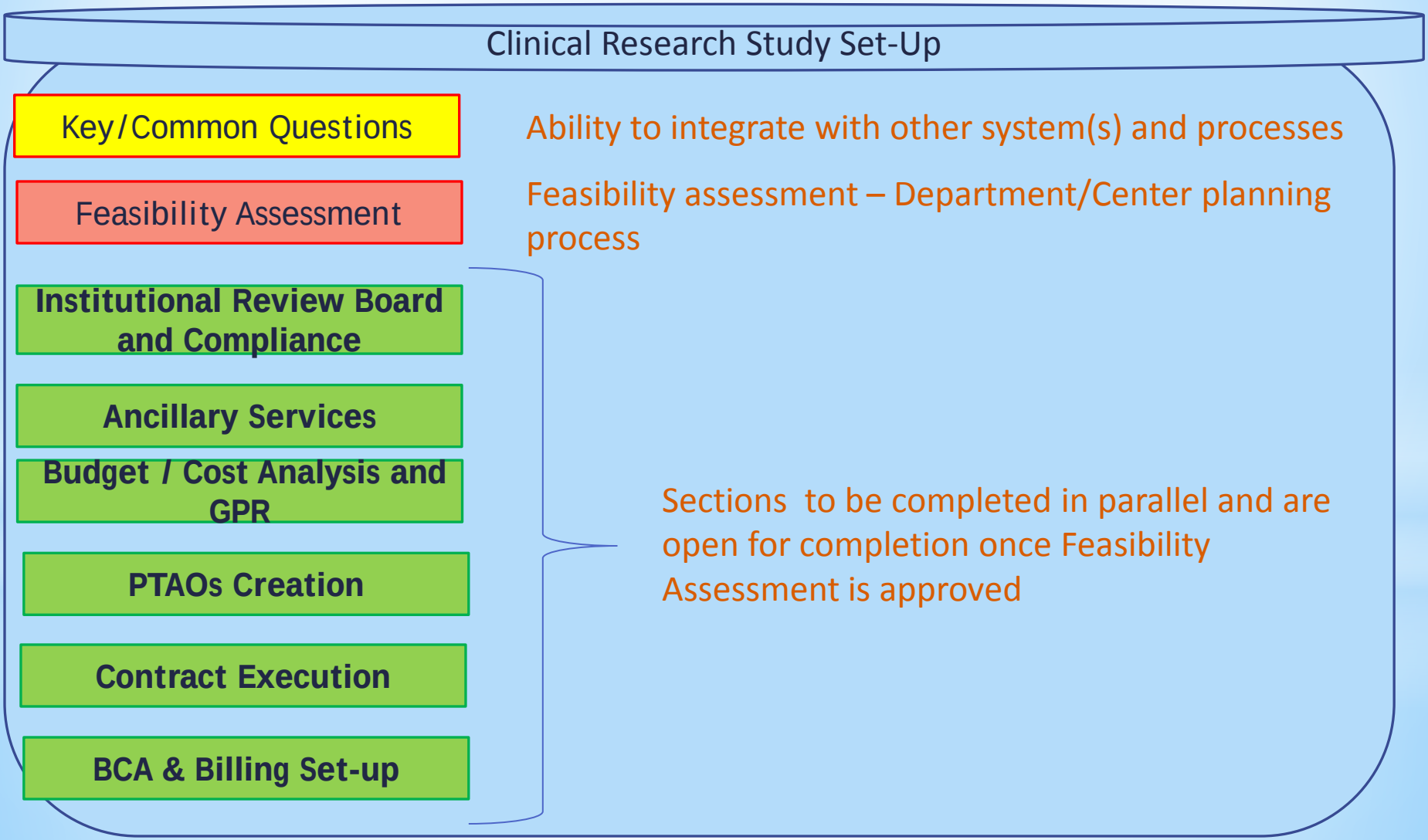
START: PI has a protocol (sponsor) or protocol design
AND Established Funding Source (Grant, Contract, Internal)

Clinical Research Study Set-Up

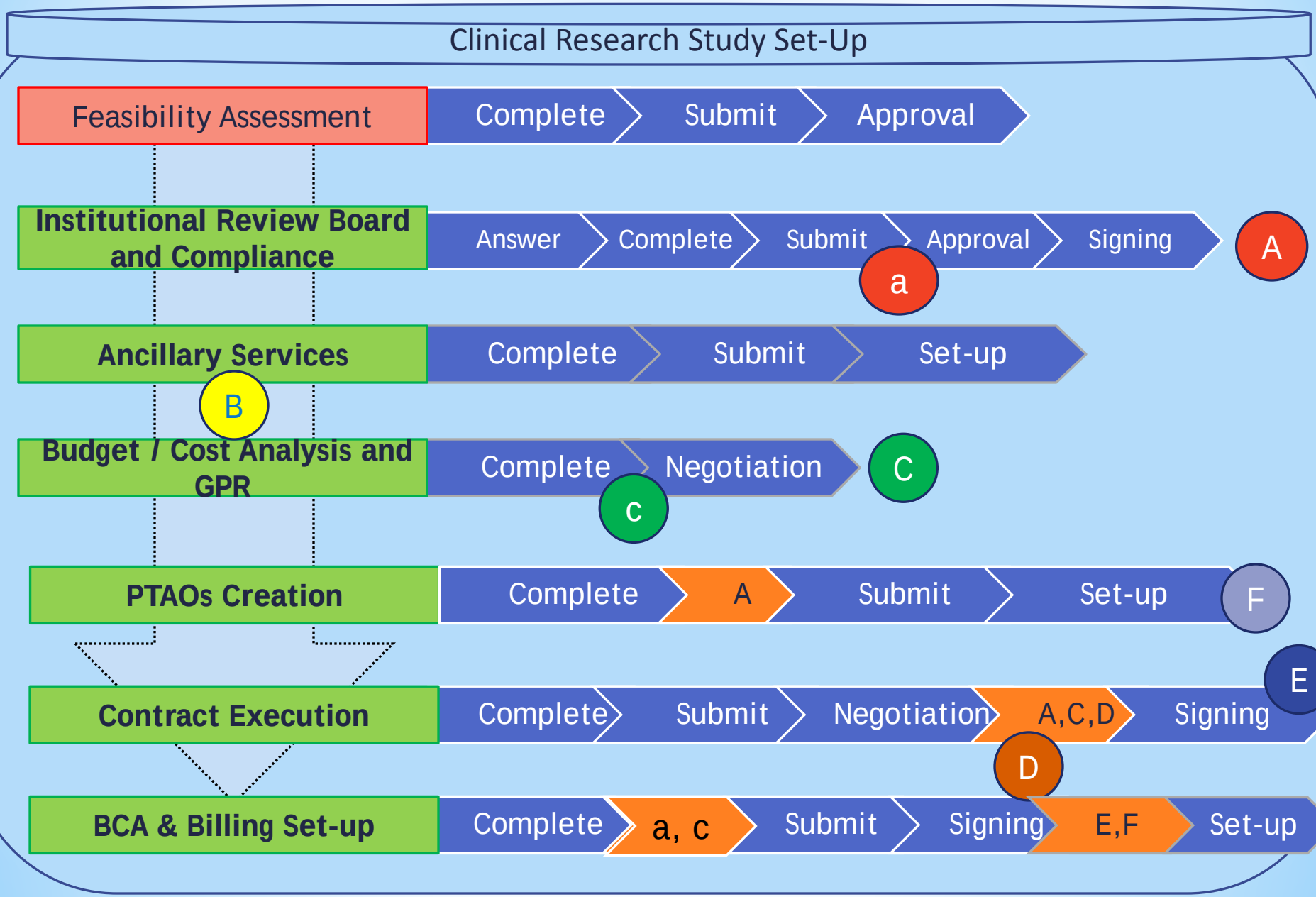
- Key/Common Questions
- Feasibility Assessment
- **Institutional Review Board and Compliance**
- **Ancillary Services**
- **Budget / Cost Analysis and GPR**
- **PTAOs Creation**
- **Contract Execution**
- **BCA & Billing Set-up**

- Automated workflow
- Ability to see reasons for rejections/comments
- Email notifications
- Ability to sign electronically
- Ability to manage documents
- Portfolio, Reporting
- Visibility and transparency
- Status and map of the process
- Integrate internally and externally

Concept of target condition - dependency



Evaluating submission flow



Clinical Research Study Set-Up

Key/Common Questions

Feasibility Assessment

START: PI has a protocol (sponsor) or protocol design AND Established Funding Source (Grant, Contract, Internal)

PI/Study Team:

- **Initiate a new clinical research study set-up workflow; unique id #**

PI/Study Team:

- **Complete** study generic and "key" information
- **Receive** system generated "key" answers
- **Complete** Feasibility Assessment questions
- **Submit** Feasibility Assessment to Department/Center review

Department/Center committee:

- **Approve/Reject** proceeding with the study set-up

If Approved by Department/Center committee:

PI/Study Team:

- **Complete** IRB HSR Protocol – submission questions (Opportunities/Phases)

Opportunities for integration

Export from Clinical Research Study Set-Up -> Import into IRB Protocol Builder:

- Unique id #
- Study generic information and other “common” answers

Opportunities/Phases:

- No additional information will be exported-imported
- IRB “key” answers
- IRB HSR Protocol submission

IRB Protocol Builder

PI/Study Team:

- **Search** by unique id #
- **Retrieve** available information, complete if necessary
- **Submit**
- **Receive** system generated templates

IRB opportunities for integration - 1

Export from IRB Protocol Builder -> Import into Clinical Research Study Set-Up
Links to system generated templates

Complete IRB-HSR Templates
Complete required Compliance forms

Clinical Research Study Set-Up

Institutional Review Board and Compliance

PI/Study Team:

- **Upload** IRB-HSR completed templates
- **Upload** required compliance forms – opportunity to streamline and automate
- **Submit** to IRB's review

IRB Staff:

- **Review** the information
- **Manage documents**
- **Pre-review Complete,** *Download submission from IRB Protocol Builder to IRB Online*
- **Route for electronic signatures** (via DocuSign)

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IRB opportunities for integration - 2

Export from Clinical Research Study Set-Up -> Import into IRB Online:

- Unique id #
- Executed finalized Protocol
- Executed IRB Application (if sponsor protocol)
- Executed Consent form (if applicable)

IRB Online

If Approved by IRB:

- System generated Approval Assurance form
- **IRB Chair** signs electronically (via DocuSign)

Export from IRB Online -> Import into Clinical Research Study Set-Up

- Executed Approval Assurance form
- Key final/approved information

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Clinical Research Study Set-Up

Ancillary Services

Budget / Cost Analysis

PI/Study Team:

- **Complete** Ancillary Services required information
- **Upload** Ancillary Services required documentation
- **Submit** to Ancillary Service(s)

Ancillary Service(s):

- **Review** the information
- **Manage documents**
- **Complete/confirm set-up**

PI/Study Team:

- **Complete** Budget/Cost Analysis required information
- **Upload** Budget required documentation
- **Submit** Grant Pricing Request to Clinical Trials Office for completion

Clinical Trials Office:

- **Review** the information
- **Complete** Grant Pricing Request Opportunity to system generate

PI/Study Team:

- **Upload** Budget sent to Sponsor C
- **Upload** Final/Negotiated Budget C

Clinical Research Study Set-Up

PTAOs Creation

Billing Set-up

Office of Grants and Contracts or Office of Sponsored Programs:

- **Complete** PTAO information
- **Submit** to OSP Account Create

OSP Account Create:

- **Confirm** set-up
- **Provide** information

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PI/Study Team:

- **Complete** Billing required information
- **Submit** to Clinical Trials Office

Clinical Trials Office:

- **Review** the information

If Approved by Clinical Trials Office

- **Route for electronic signatures** (via DocuSign)

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Contract Execution

PI/Study Team:

- **Complete** Contracts negotiation required information
- **Route for electronic signatures** (via DocuSign)
- **Upload** Clinical Trials Agreement template
- **Submit** to Office of Grants and Contracts

Office of Grants and Contracts:

- **Review** the information
- **Manage documents (negotiation)**

If Approved by Office of Grants and Contracts

- **Route for electronic signatures** (via DocuSign):
  - Contract negotiation required information
  - Clinical Trials Agreement

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Opportunities for integration

Export from Clinical Research Study Set-Up -> Import into ResearchUVa

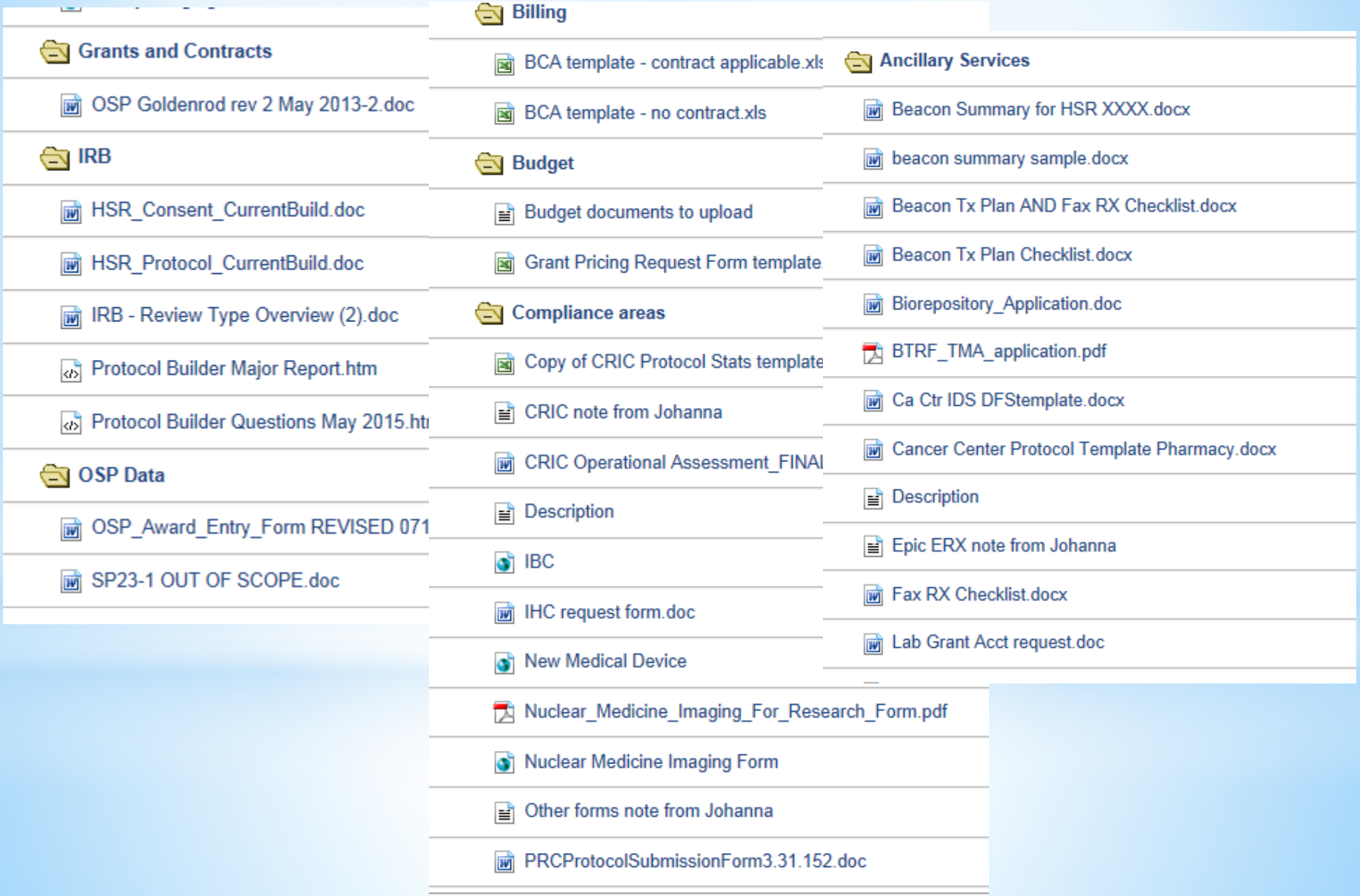
- Unique id #
- Executed Contract negotiation required information (Goldenrod)
- Executed Clinical Trials Agreement
- Executed IRB Approval Assurance form
- PTAO request information

Additional integration to explore

Explore Integration from ResearchUVa for Pre-Award tasks

OnCore, an Example of a Clinical Trials Management System

Data Points


Grants and Contracts
OSP Goldenrod rev 2 May 2013-2.doc
IRB
HSR_Consent_CurrentBuild.doc
HSR_Protocol_CurrentBuild.doc
IRB - Review Type Overview (2).doc
Protocol Builder Major Report.htm
Protocol Builder Questions May 2015.ht
OSP Data
OSP_Award_Entry_Form REVISED 071
SP23-1 OUT OF SCOPE.doc
Billing
BCA template - contract applicable.xls
BCA template - no contract.xls
Budget
Budget documents to upload
Grant Pricing Request Form template
Compliance areas
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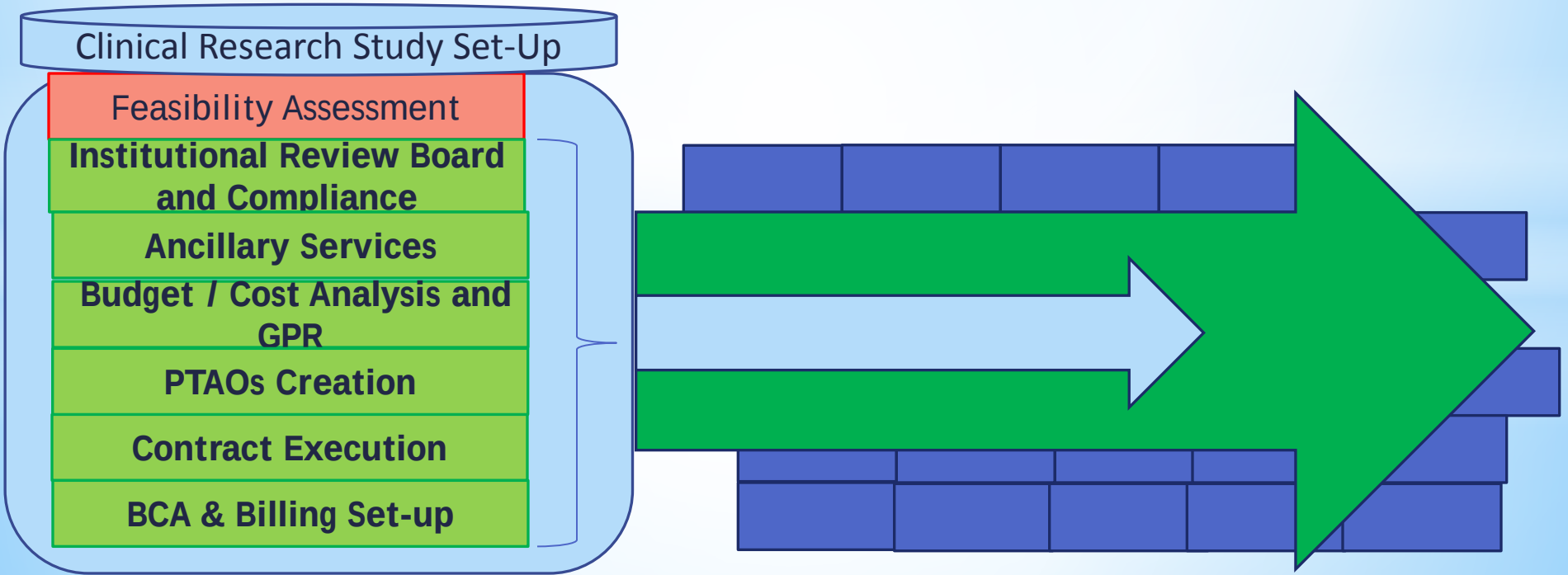
CRIC note from Johanna
CRIC Operational Assessment_FINAL
Description
IBC
IHC request form.doc
New Medical Device
Nuclear_Medicine_Imaging_For_Research_Form.pdf
Nuclear Medicine Imaging Form
Other forms note from Johanna
PRCProtocolSubmissionForm3.31.152.doc
Ancillary Services
Beacon Summary for HSR XXXX.docx
beacon summary sample.docx
Beacon Tx Plan AND Fax RX Checklist.docx
Beacon Tx Plan Checklist.docx
Biorepository_Application.doc
BTRF_TMA_application.pdf
Ca Ctr IDS DFStemplate.docx
Cancer Center Protocol Template Pharmacy.docx
Description
Epic ERX note from Johanna
Fax RX Checklist.docx
Lab Grant Acct request.doc

Industry metrics & where we start

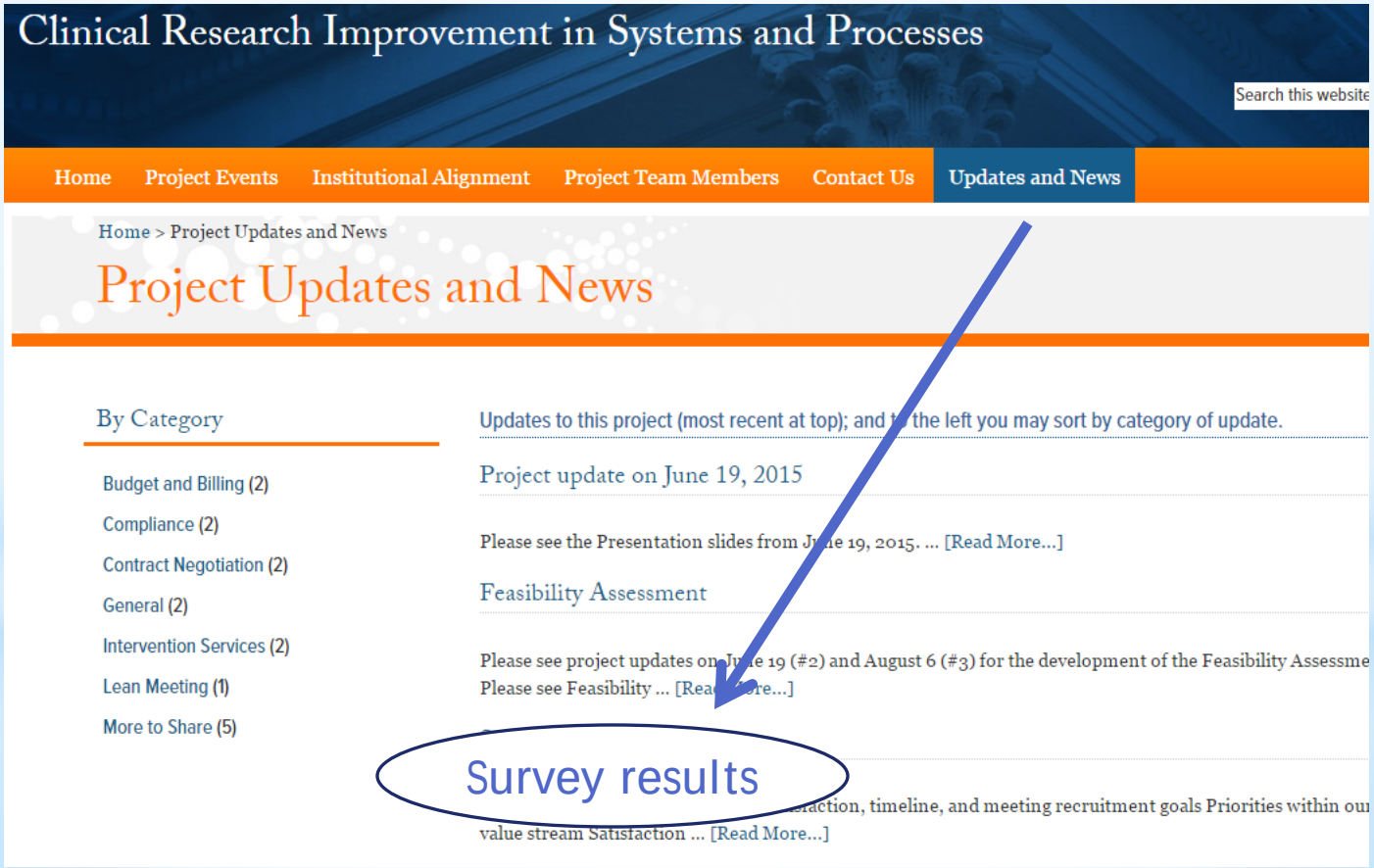
Pfizer, 2009:

- "The time from final approved protocol received at the site until the site enrolls first patient <= 100 days"
- "The time from final approved protocol received at the site until final contract signed <= 30 Days"



Open-ended survey results

Survey results have been shared with the project advisory.



Next steps – next 6 weeks:

Data points: flow and integration

Process: submission, signatures

Feasibility assessment: wrap-up tool, opportunities for training

Incorporate survey results

Creating baseline, setting success metrics

Automation opportunities

Next steps, stay connected

Next meeting:

- An invitation will be sent for the week of September 14

Stay connected:

- Let us know if you want to be more involved
- Check project website: http://cr.med.virginia.edu

Thanks to the best workgroup ever

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