

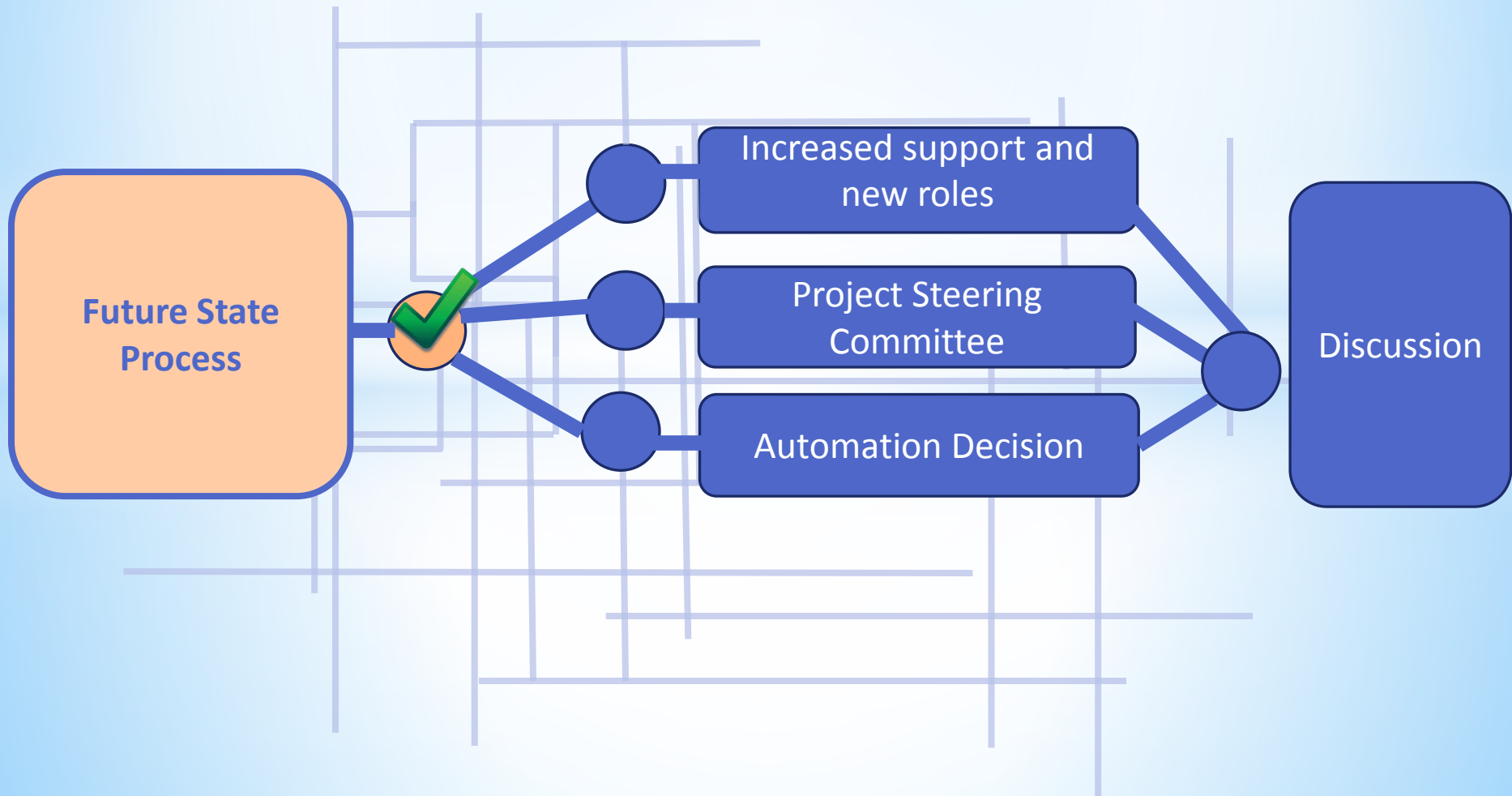
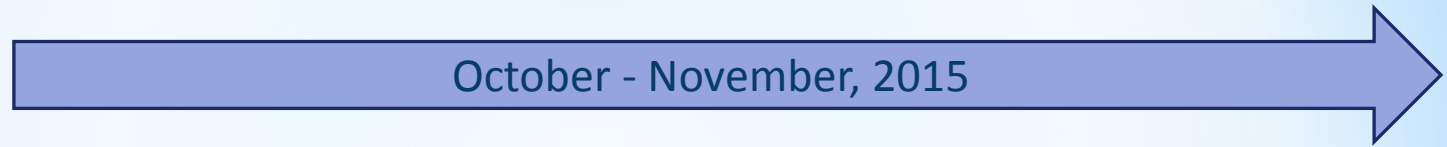
Clinical Research Improvement in Systems and Processes - CRISP



November 17, 2015



The map of our journey - agenda



Doug Johnson joining the Workgroup as Business Analyst

Cricket Birk, RN CCRN

Clinical Research Coordinator, Department of Anesthesiology

Sandra Burks, RN, BSN, CCRC

Associate Director, Surgical Therapeutic Advancement Center

Stewart P. Craig, MS

Assistant Dean for Research Administration

Director, Office of Grants and Contracts

Lori Elder, RN BSN CCRA

Director, SOM Clinical Trials Office

Susie Hoffman, RN BSN CIP

Director: IRB for Health Sciences Research

Doug Johnson, MBA

Business Analyst, School of Medicine

Lynn Koplín, M.A., CRCP

Assistant Director of Contracts, Office of Sponsored Programs

Johanna Loomba, BS, CCRC

Director, UVA Neurosurgery Clinical Research

Goga Radakovic, MD, CCRC

Director, Office of Clinical Research, Cancer Center

Catherine A. Reniere, MA

Cancer Informatics Program Manager

Linda Duska formally joining the Project Leadership team

Linda R. Duska, MD, MPH

Professor of Obstetrics and Gynecology
Interim Associate Dean for Clinical Research

Thea Grover-Patrick, MBA

Director, Strategic Initiatives, Health System

Sean Jackson, D.M.A

Chief Information Officer, School of Medicine & University of Virginia Physicians Group

Paul V Targonski, MD, PhD, MPH

Associate Professor of Department of Public Health Sciences and
Director for Clinical Research Initiatives

Establishing a Steering Committee

Elizabeth H. Adams

Assistant Vice President for Research Administration, Office of Sponsored Programs,
University of Virginia

James A. Amato, MBA

Chief of Clinical Ancillary Services and
Interim Chief Operating Officer for Hospital and Clinics Operations

David J. Hudson, PhD

Associate VP for Research, University of Virginia

Katherine L. Peck, MBA

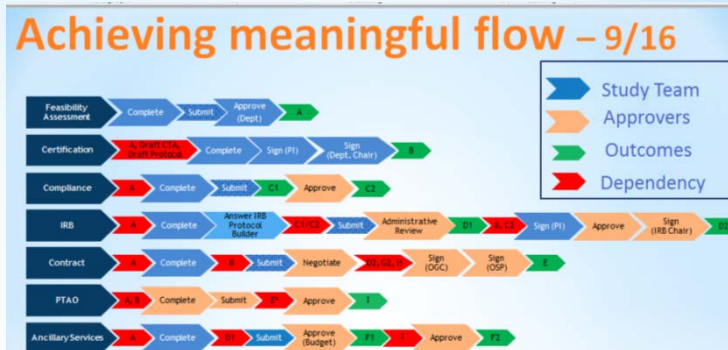
Chief Operating Officer, School Of Medicine

Margaret A. Shupnik, Ph.D.

Professor of Medicine and Physiology, Division of Endocrinology and Metabolism
Senior Associate Dean for Research

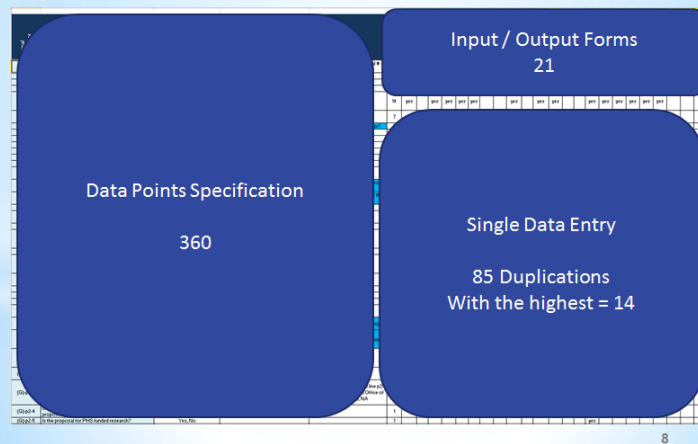
Workgroup meeting with SOM IT

- Future State Flow
- Future State Data Points
- Functional Requirements (92 items)



ID	Function	Requirement	Additional Information	Category	Trigger Prior Action	User Affected	Users Involved	IT Feedback	Priority
72	Ancillary Services	Ancillary Services: final approval of processes	Approve within CRISP	PTAD	IDS				
73	Ancillary Services	EPIC order set: enter, save, submit	See Data Points and process diagram	Ancillary Services	IDS				
74	Ancillary Services	EPIC order set: approval by EPIC	See Data Points and process diagram		EPIC				
75	Ancillary Services	EPIC order set: approval by IDS	visible in CRISP		IDS				
76	Ancillary Services	EPIC order set: Final approval of order set by PI and IDS	See Data Points and process diagram		PI				
77	Ancillary Services	Communication between Epic and IDS							
78	Ancillary Services	<u>Ancillary Services includes the following areas:</u> (Need to determine what is needed from CRISP to initiate services) 1) IDS - Investigational Drug Services- Priority 2) Ambulatory Clinic/Hospital/Nursing Unit/Cancer Center Infusion 3) BTRF - Biorepository and Tissue Research Facility 4) Clinical Laboratories 5) Clinical Research Unit 6) Radiology and Medical Imaging 7) Therapy Services such as Physical Therapy, Occupational Therapy	See Data Points and process diagram						
79	AR	Enroll Subjects				IRB, Contract, EPIC, Billing	PI + CFC		Configuration
80	AR	Signatures: transparent in process to select designers and/or alternates	Divorce	System: Infrastructure					Configuration
81	Post Approval	Ability to initiate a workflow if any changes are required to the approved study information. Save and Submit. Examples for changes: • Personnel Changes • Change in # of Subjects to be Enrolled (e.g. sign a consent form) • Change of Dates (e.g. changing from open to enrollment to closed to enrollment, follow-up only) • Amendments and Modifications with Consent Changes • Addition of "consideration for "Outlier Exclusion to BDD"							Configuration
82	Post Approval	Ability to review and approve changes to the studies. The VS Owner or all the approvers will need to be notified.							Configuration
83	Post Approval	Ability to trigger notifications to various users for annual continuation. It is possible that no changes are required, just reporting.							Configuration
84	Post Approval	Ability to trigger notifications to various users for a 5 year updates							Configuration
85	AR	Interface information from CRISP to CTMS	CRISP -> CTMS	Integration					Configuration
86	AR	Interface information from CRISP to Research/VA	CRISP -> Research/VA	Integration					Configuration
87	Post Approval	Ability to collect, notify about, and report on information about Adverse Events and Serious Adverse Events (at UVA and outside of UVA)	CRISP or CTMS (Occurs)	System: Research					Configuration
88	Post Approval	Enroll Subjects: Incorporate ability to record study statistics: # patients, etc.,	CRISP or CTMS (Occurs)	System: Research					Configuration
89	Post Approval	Interface information from CRISP to clinicians.gov	CRISP -> Clinicians.gov	Integration					Configuration
90	Post Approval	In the absence of the interface with clinicians.gov - generate a "clinicians.gov" reportable with all the necessary information that is required for clinicians.gov entrance							Configuration
91	AR	Ability to get information from the Integrated System(Oracle) or LDAP or Peopletable to get information about PI and other	Integrated System (Oracle)/LDAP/Peopletable -> CRISP	Integration					Customization
92	AR	Interface to IRB Online "Protocol creation" module Additional items to discuss	CRISP -> IRB Online PIs may use IRB Protocol Builder to test the ideal/proof of concept idea. How does this impact our pipeline/workload for IRB? What are the opportunities	Integration					Integration

Data points – 9/16



Automation Decision - *platform*

- Using highly configurable Workflow platform developed by SOM IT
- **Clinical Faculty Hiring** – since April 2014:
 - More than 200 offers extended and accepted.
 - From submission to SOM HR to Reaching candidate = average 5 days. It includes review, approval, signing.
 - From submission to SOM HR to Candidate's acceptance = average 18 days.
- **Research and Instructional Faculty Hiring** – since October 2015:
 - 33 workflows initiated.
 - 8 offers extended and accepted.
 - Average time start to acceptance = 4 days.
- **Faculty Merit increase 2015** – August 2015:
 - More than 300 documents generated and signed.

Automation Decision

- Using highly configurable Workflow platform developed by SOM IT
- Most requirements can be done using configuration (no programming will be involved)
- Ability to support UVa Health Sciences Research Study Start-up
- SOM IT Resource secured to start the configuration in January 2016
- Required steps:
 - Finalize data points structure and flow
 - Finalize integration points with existing systems
 - Create security model
 - Estimate programming requirements
- Considerations – workgroup's commitment to continue
 - Phased approach, pilot
 - Value stream ownership
 - Change management

Study teams will initiate Health Science Research study start-up workflows



- *Login with Netbadge*
- Three steps process:
 1. Feasibility Assessment & Commitment
 2. Approvals
 3. Set-up

1. Feasibility Assessment & Commitment

Study Common Information

Sponsor Information (if applicable)

Scientific Review

Subject/Patient Needs and Availability

Budget Consideration and Cost Analysis

Methodology/Operational Considerations

Features:

- Data points (required, optional)
- Single data entry
- Notes, Revisions
- Managing documents
- Email notification
- Reporting

• Study Team:

SUBMIT

• Department Committee:

Approve

Return

Reject

• Electronic Signing:

DocuSign[®]



2. Approvals: *smart dependency & in parallel*

Regulatory
(what's applicable)

IRB

Contract

Ancillary Services
(what's applicable)

Budget/Cost Analysis and Grant Pricing

Billing Coverage Analysis

Features:

- Data points & validations
- Single data entry
- Notes, Revisions
- Creating & Managing documents
- Email notification
- Reporting

• Study Team:

SUBMIT

• Approvers:

Approve

Return

• Electronic Signing:

DocuSign



3. Set-up: *smart dependency & in parallel*

PTAO set-up

Epic Order Set

Billing set-up

Negotiations
& Signing

Ready to Enroll!



Features:

- Email notification
- Reporting
- Notes
- Managing documents
- Finalizing checklists
- Integrations

- Electronic Signing: 



Visibility at every step of the study

Seeing the path and knowing where things are at any point in time

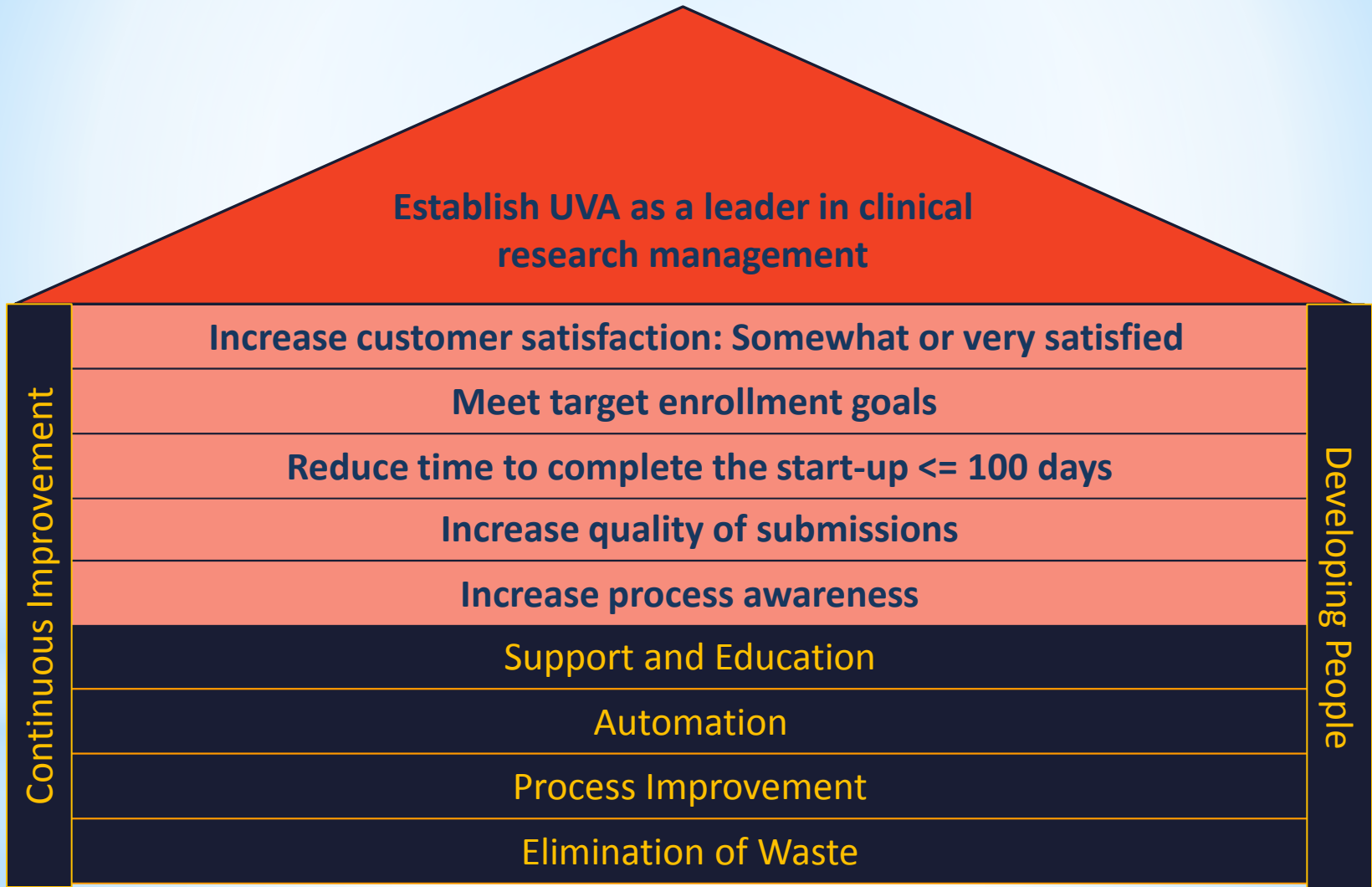


Visibility on the portfolio of studies

*Business reporting
and analytics
Enhancing decision
making*



Focusing on the foundation



Discussion

- What are you hearing?
- What are you seeing?
- What are you not saying?
- If things were improving, what stories would people tell?

- Your input:
 - Increasing awareness
 - Venue of communication

Next steps, stay connected

Next meeting:

- An invitation will be sent for January 2016

Stay connected:

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

