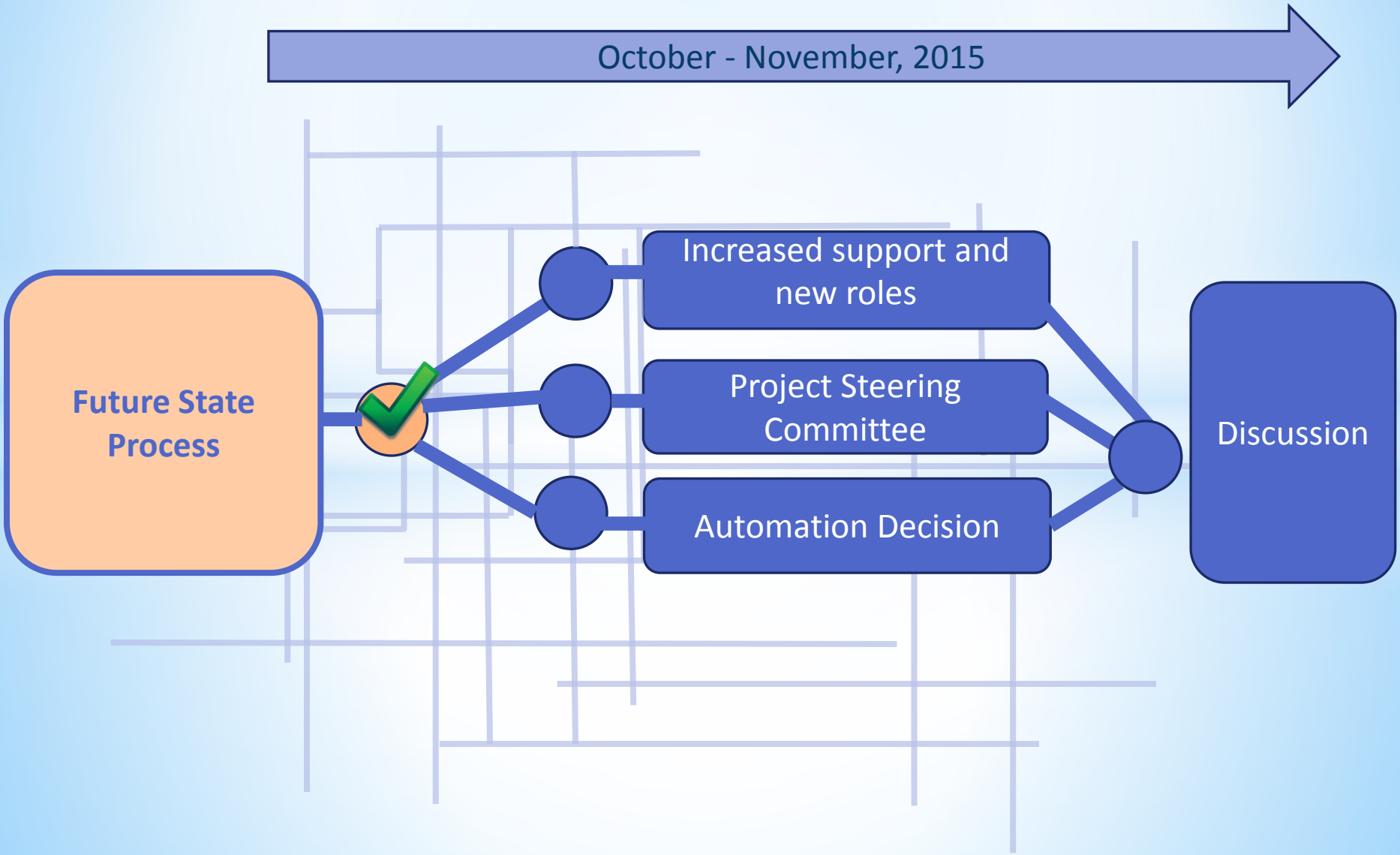
Clinical Research Improvement in Systems and Processes - CRISP

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 Koplin, 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

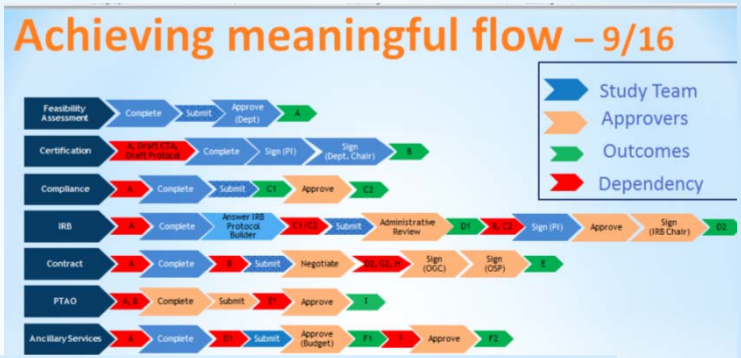
David J. Hudson, PhD
Associate VP for Research, University of Virginia

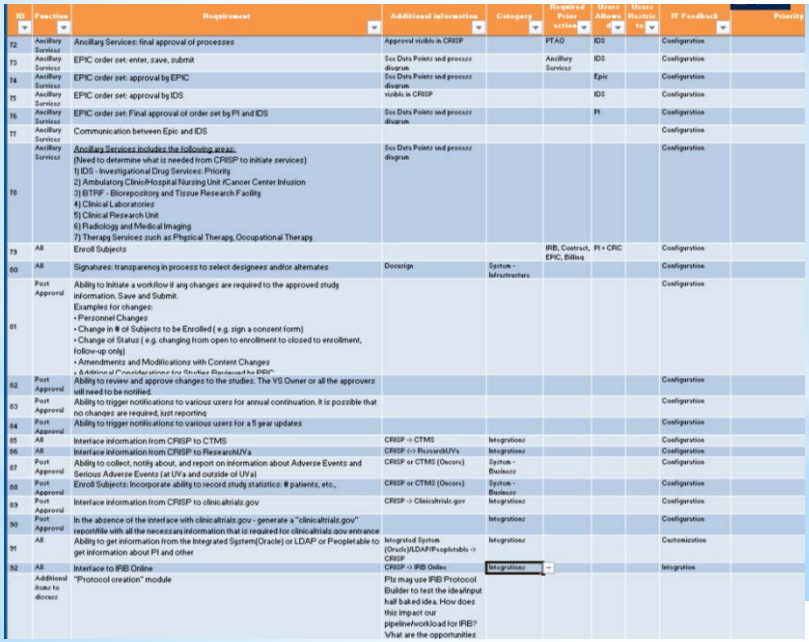
Katherine L. Peck, MBA
Chief Operating Officer, School Of Medicine

Margaret A. Shupnik, Ph.D.
Professor of Medicine and Physiology, Division of Endocrinology and Metabolism
Senior Associate Dean for Research

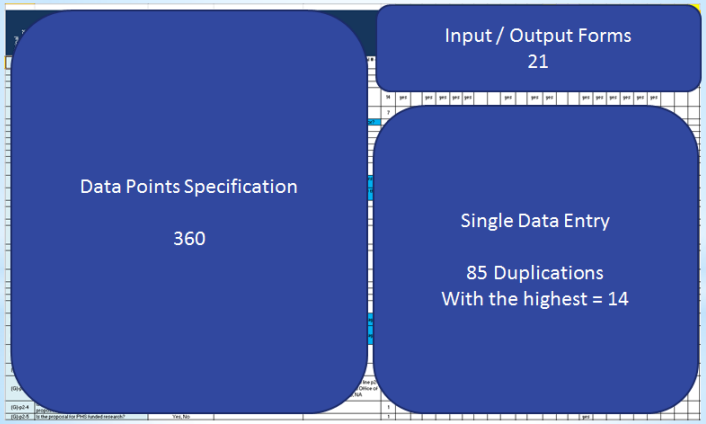
Workgroup meeting with SOM IT

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





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:
- Approvers:
- Electronic Signing:

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: DocuSign

Visibility at every step of the study

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

Contracts

Billing

EPIC

IRB

PTAO

Regulatory

Ancillary

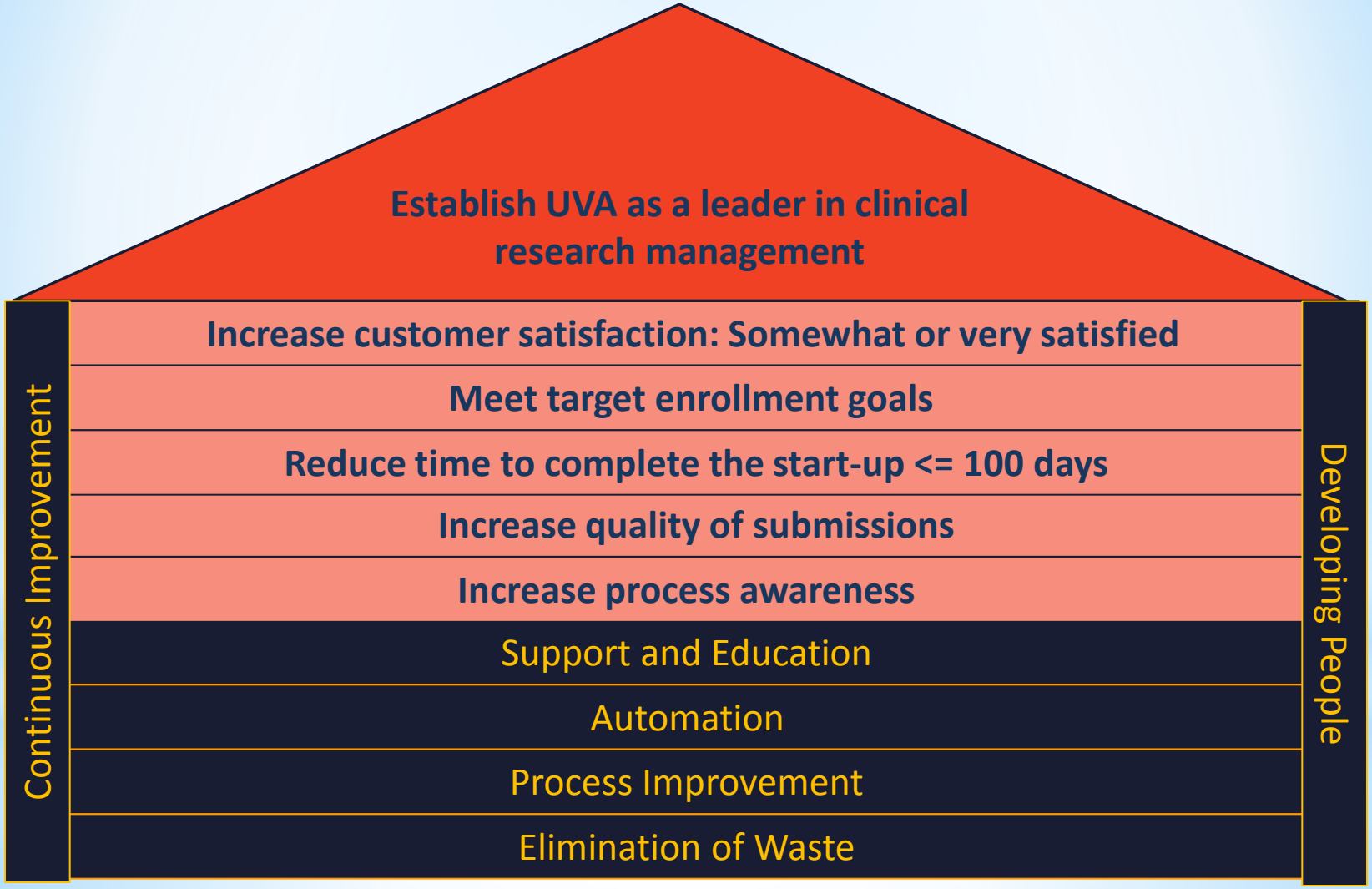
Feasibility Assessment

Documents and revisions

Budget

Visibility on the portfolio of studies

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