The map of our journey - agenda

August – September, 2015

Feasibility Assessment concept, Target condition and integrations

- Survey and Peer Institutions
- Signatures
- Flow and Dependency
- Data Points
- Engaging IDS and ISPRO
- Metrics and Baseline

Your Feedback: Areas of our Focus
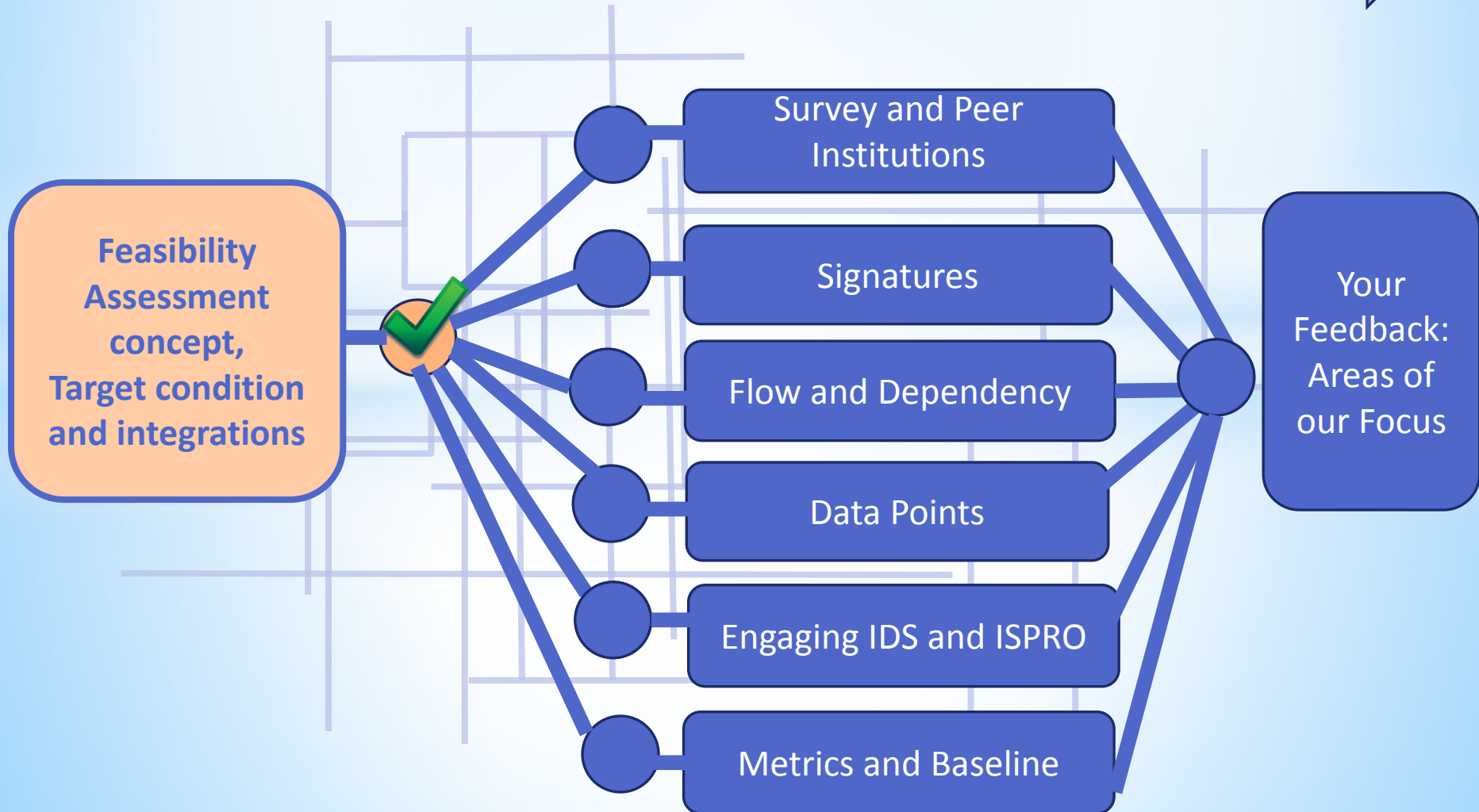
Survey open-ended results

Improve process and systems

Simplify submission and provide visibility

Reduce turnaround time

And, <u>additional meaningful suggestions</u>:
- Align expectations: Tell us what/when to expect.
- Give us ways to find contacts, resources, and items you require us to complete.
- Provide unified responses to requirements.
- Increase [our] ability to prepare and negotiate budget.
- We advocate for improved feasibility assessment and need help.
- Provide more support, especially for researchers and study coordinators new to our process.
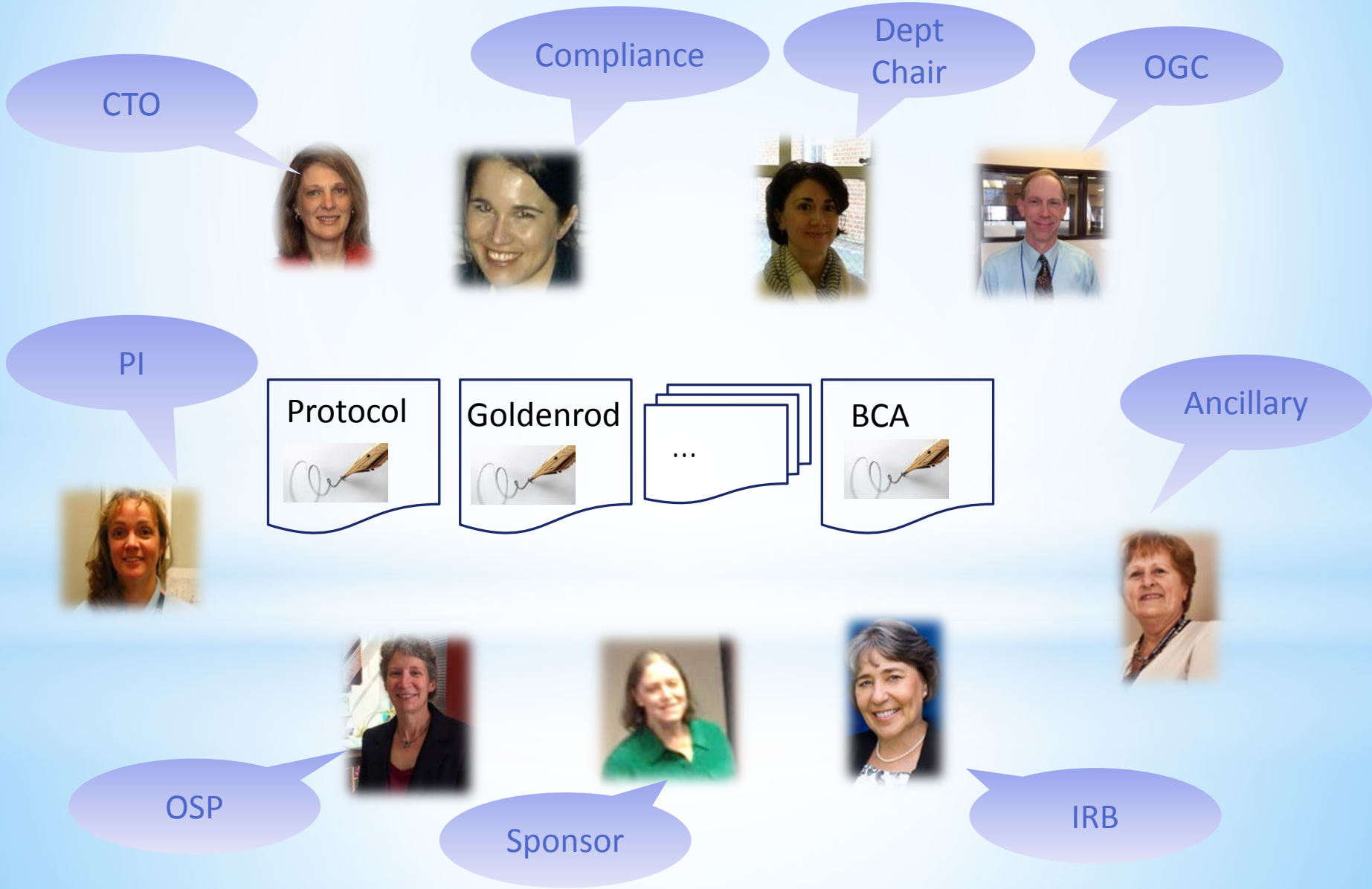- Are we an overly risk adverse institution?

Learning from peer institutions

- There is no "silver-bullet" system
- Change management and planning
- Support is typically underestimated
- Importance of value stream ownership and IT support

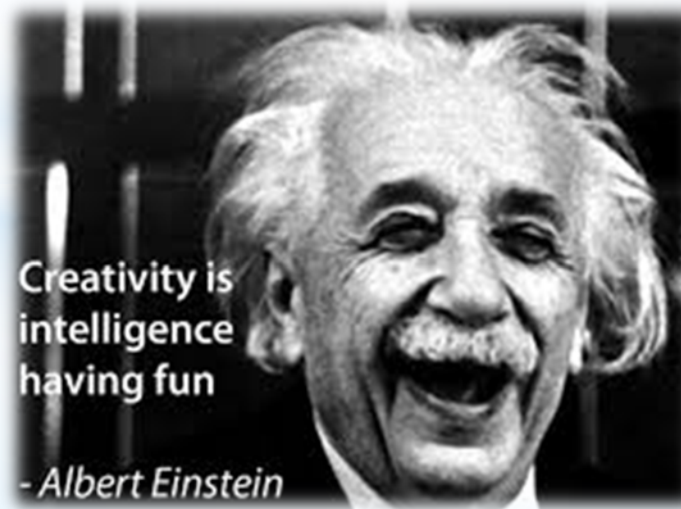# Examples of our
Process Improvement

Our Gemba, "the real place"

Signatures success story

7

Creativity is
intelligence
having fun

- Albert Einstein

Achieving meaningful flow

Legend	
Study Team	(blue)
Approvers	(orange)
Outcomes	(green)
Dependency	(red)

Feasibility Assessment: Complete → Submit → Approve (Dept) → A

Certification: A, Draft CTA, Draft Protocol → Complete → Sign (PI) → Sign (Dept. Chair) → B

Compliance: A → Complete → Submit → C1 → Approve → C2

IRB: A → Complete → Answer IRB Protocol Builder → C1/C2 → Submit → Administrative Review → D1 → B, C2 → Sign (PI) → Approve → Sign (IRB Chair) → D2

Contract: A → Complete → B → Submit → Negotiate → D2, G2, H → Sign (OGC) → Sign (OSP) → E

PTAO: A, B → Complete → Submit → E* → Approve → I

Ancillary Services: A → Complete → D1 → Submit → Approve (Budget) → F1 → I → Approve → F2

Epic Order Set: F2 → Complete → Submit (to Epic) → Approve 1 → Approve 2 → Submit (to PI) → Approve → Approve → J

Budget / Cost Analysis and Grant Pricing Request: A → Complete → Submit → Approve → F1 → G1 → Negotiate → G2

Billing Coverage Analysis: A → Complete → D1, G1 → Submit → Approve → Sign (PI) → H

Billing Set-up: H, I → Approve → K

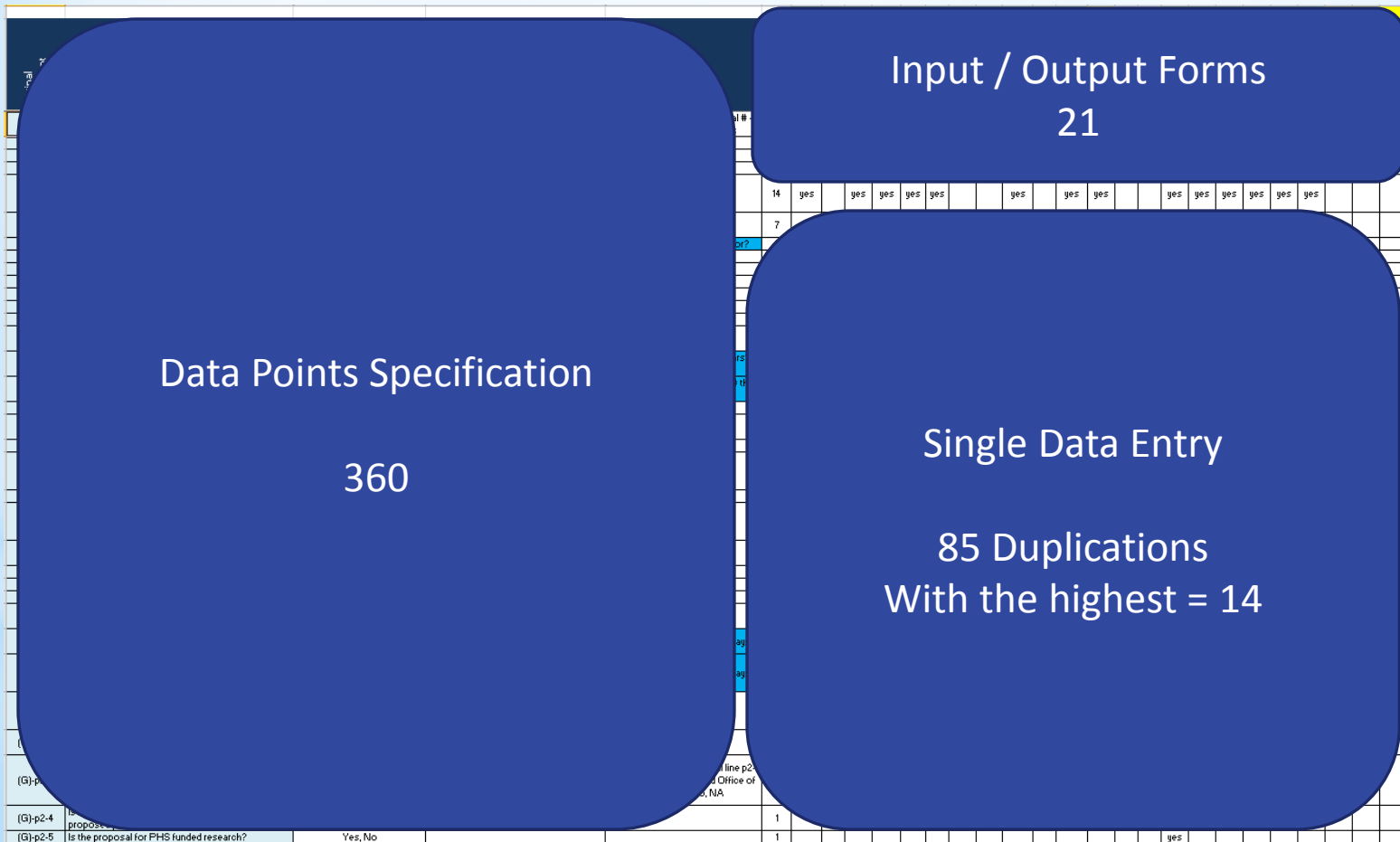**Enroll Subjects:** D2 + (E, J, K) as applicable → Ready!

Increasing quality of the submission – current focus:

Ancillary Services: thanks to IDS

Compliance: thanks to IRB, ISPRO &
SOM Information Security and Risk Management Officer

Achieving one data entry - data points

Data points - *in process,*
lots of details & good work

Input / Output Forms
21

Data Points Specification

360

Single Data Entry
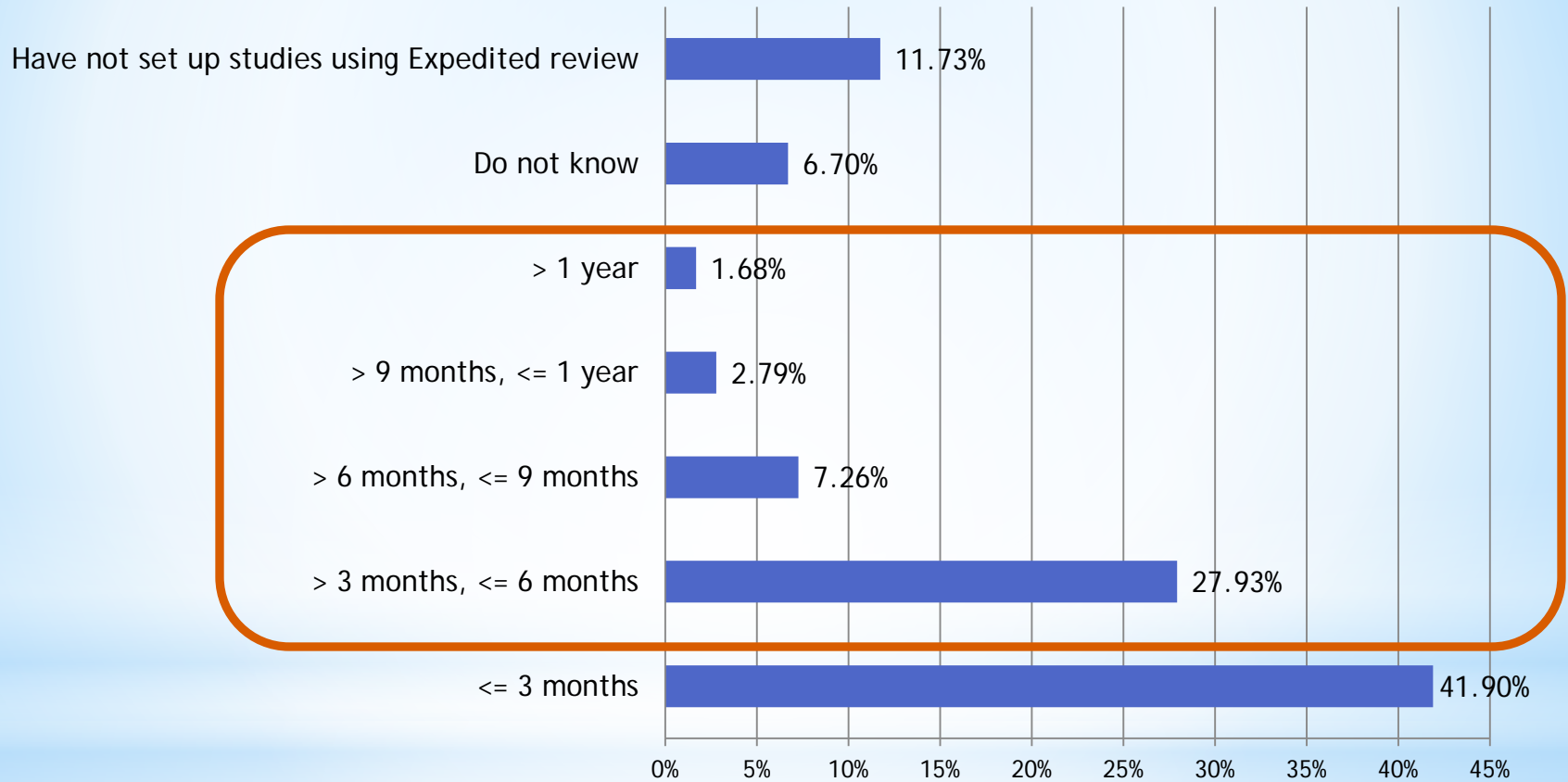
85 Duplications
With the highest = 14

11

Three important metrics

1. Work-in-process
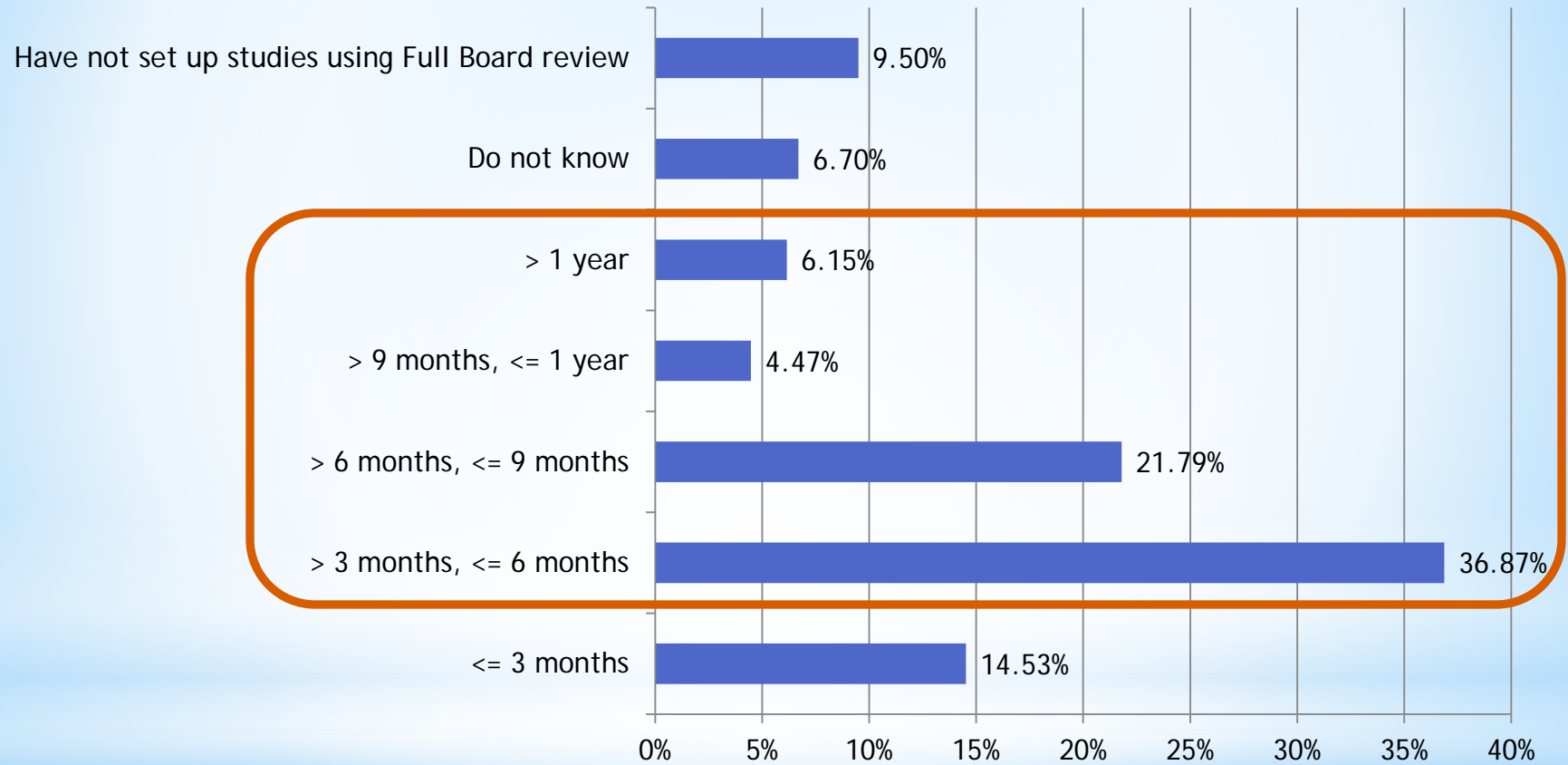2. Time to complete the study start-up
3. Satisfaction

Managing work-in-process

will lead to on-time delivery,

which in turn will lead to higher enrollment rate and
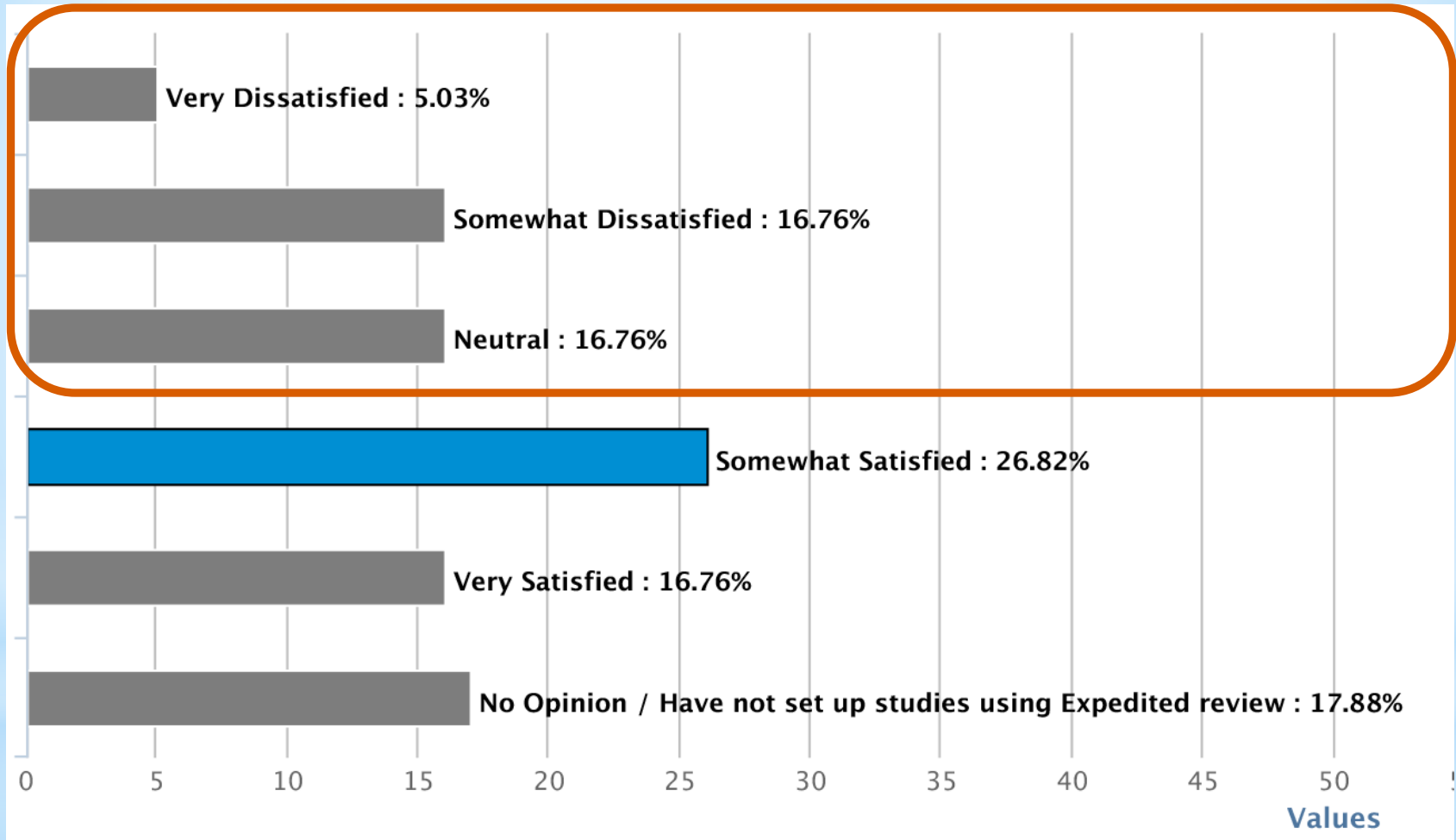
ultimately increased satisfaction.

Time: entire start-up, using Expedited

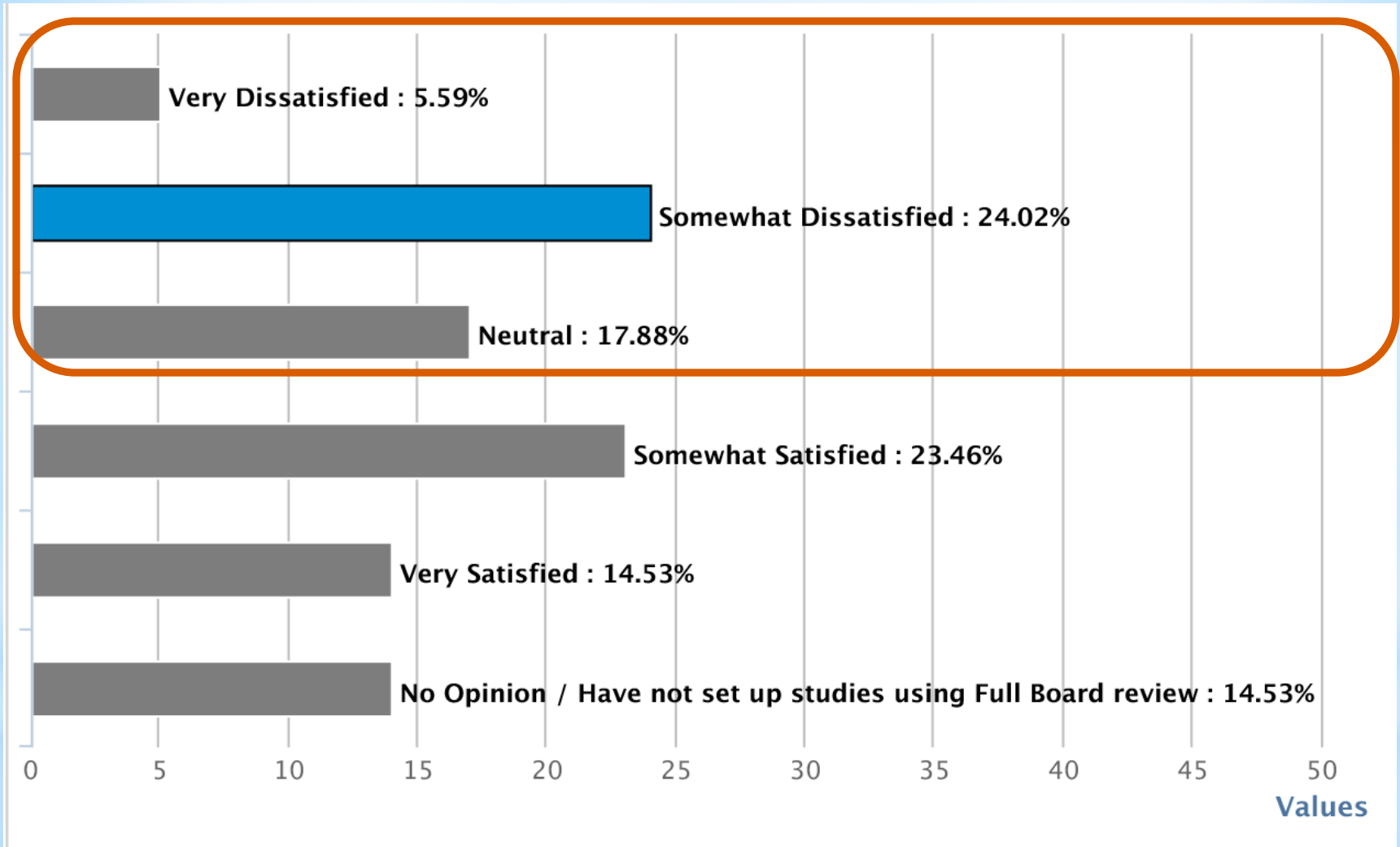| Category	Percentage
Have not set up studies using Expedited review	11.73%
Do not know	6.70%
> 1 year	1.68%
> 9 months, <= 1 year	2.79%
> 6 months, <= 9 months	7.26%
> 3 months, <= 6 months	27.93%
<= 3 months	41.90%

Time: entire start-up, using Full Board

Have not set up studies using Full Board review	9.50%
Do not know	6.70%
> 1 year	6.15%
> 9 months, <= 1 year	4.47%
> 6 months, <= 9 months	21.79%
> 3 months, <= 6 months	36.87%
<= 3 months	14.53%

Satisfaction: entire start-up, using Expedited

Very Dissatisfied : 5.03%

Somewhat Dissatisfied : 16.76%

Neutral : 16.76%

Somewhat Satisfied : 26.82%

Very Satisfied : 16.76%

No Opinion / Have not set up studies using Expedited review : 17.88%

0   5   10   15   20   25   30   35   40   45   50

Values

Satisfaction: entire start-up, using Full Board

Very Dissatisfied : 5.59%

Somewhat Dissatisfied : 24.02%

Neutral : 17.88%

Somewhat Satisfied : 23.46%

Very Satisfied : 14.53%

No Opinion / Have not set up studies using Full Board review : 14.53%

0   5   10   15   20   25   30   35   40   45   50

Values

Choosing unique foundation

Establish UVA as a leader in clinical research management

Increase customer satisfaction: Somewhat or very satisfied

Meet target enrollment goals

Reduce time to complete the start-up <= 100 days

Increase quality: achieving perfect submission

Increase process awareness

Support and Education

Automation

Process Improvement

Elimination of Waste

Continuous Improvement

Developing People

Next steps – your feedback:

Systems – automation specification:
- **Flow and dependency** - *completed*
- **Data points** – *current focus*
- **Integrations** – *current focus*
  - *IRB Protocol Builder, IRB Online*
  - *ResearchUVa*
- **Security model** – *not started yet*

Processes:
- **Feasibility Assessment:**
  - Tool - *advisory feedback*
  - Process – *advisory feedback*
  - Education – *not started yet*
  - Implementation – *not started yet*
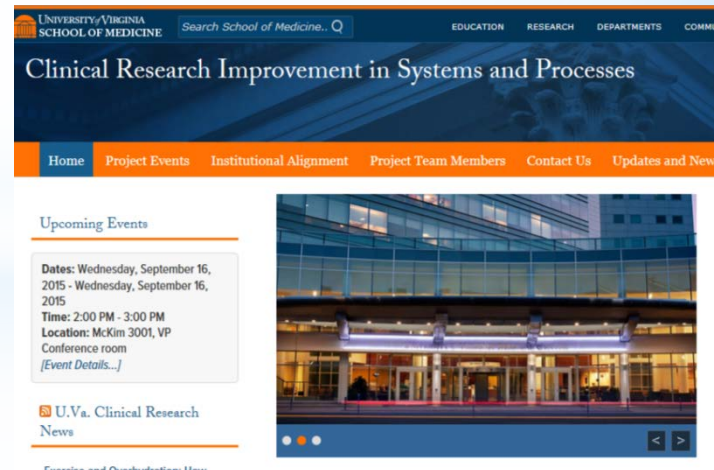- **IDS – Epic** – *current focus*
- **ISPRO** – *current focus*

Next steps, stay connected

Next meeting:

- An invitation will be sent for the week of November 2

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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