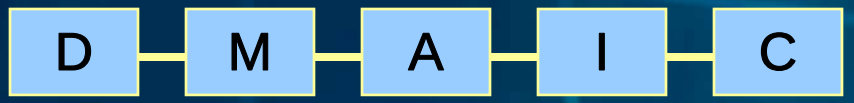
MAYO CLINIC

The Use Of Systems Engineering Tools To Improve Processes in Healthcare:

Six Sigma and Lean Improvement Methodologies as they Apply to Healthcare

QUALITY
NOTHING IS MORE IMPORTANT

Speaker Contact info



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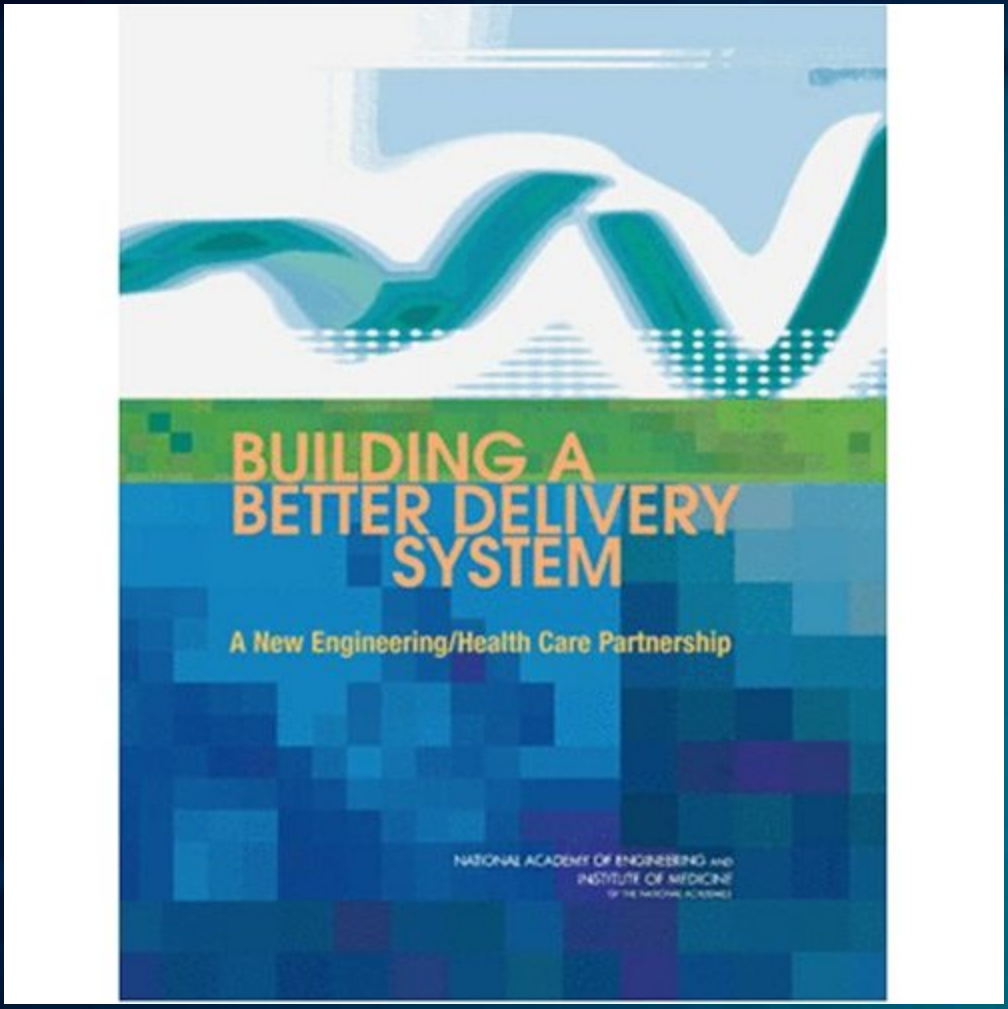
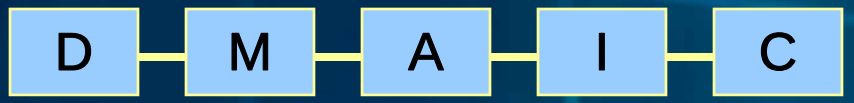
Engineering the Healthcare System

D M A I C

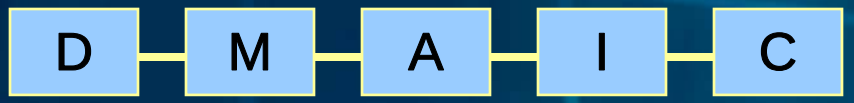


Mayo Clinic's Quality Experience



- Process Improvement Section within the Quality Management Services Department
- The Quality Academy: now part of Mayo Clinic College of Medicine.
- Mayo Clinic's System – Wide Initiatives:
  - IRB review cycle time

The IRB experience

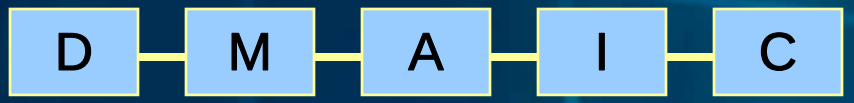


- Under federal regulations, an Institutional Review Board (IRB) is a constituted group formally designated to review and monitor research involving human subjects.

- Its' work must comply with the Federal Wide assurance agreement with the government in order to receive federal funding for research.

- Delays in making a decision may result in loss of funding and delays in patients being offered access to potential new treatments.

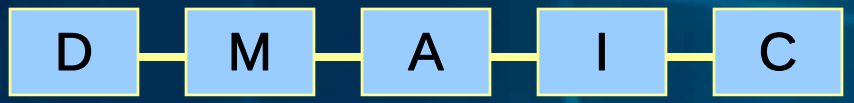
Problem & Goal



- The IRB turnaround time for protocol review has been identified as a source of dissatisfaction by the researchers and the IRB Staff.

- On average, the review of protocols took 38 days. The customers expect a more predictable and timely turnaround.

- The goal is to reduce the protocol turnaround time to no more than 21 days, while maintaining the IRB responsibility to uphold the regulations.



Team members:

Project Sponsor : Chair, Research Administration

Process Owner : IRB Medical Director

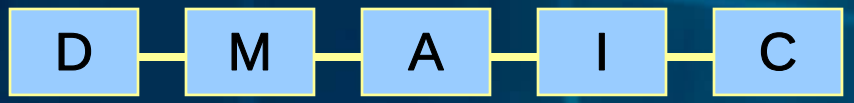
Core Team: IRB Administrator

Measurement Coordinator / IRB Operations Manager

Project Manager

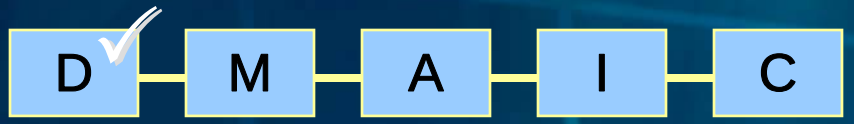
Process Improvement Expert

Results



Metrics:	Before	After
Average Cycle time	38d	16d
- 21 days compliance	27%	83%
For new submission		
Full board		

Average CT (w/out PI)	31d	11d
- 21 days compliance	38%	100%
For new submission		
Full board		



DMAIC Methodology

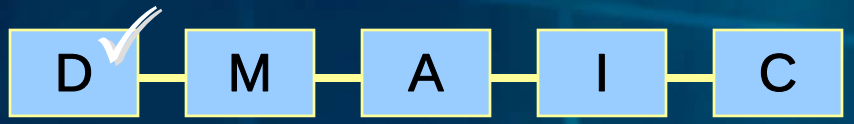
Define:

Measure:

Analyze:

Improve:

Control:



Project Charter

- An explanation for the project
- Goals and desired results in measurable terms
- Project plan and milestones
- Roles and responsibilities

Survey of Investigators

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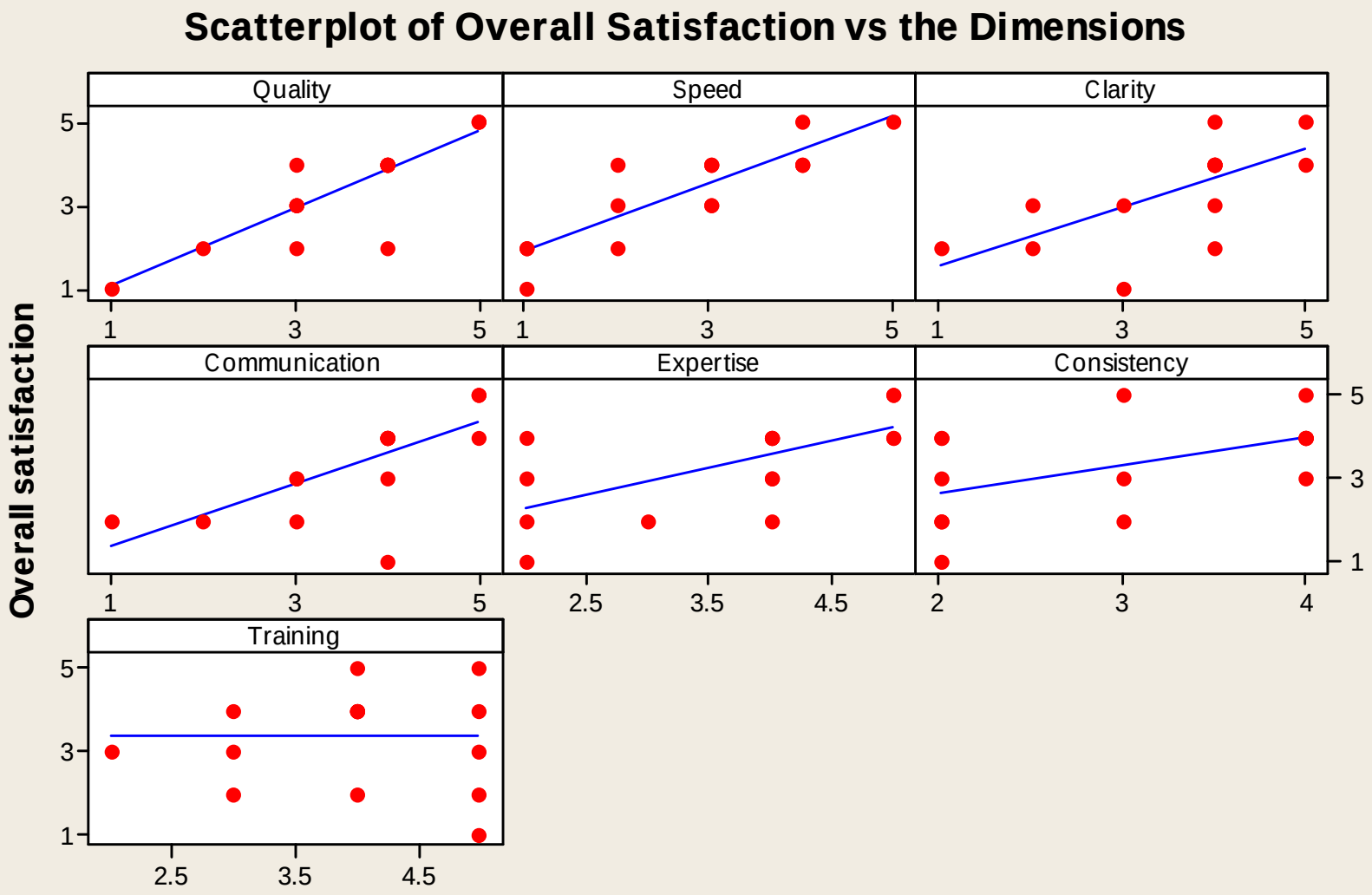
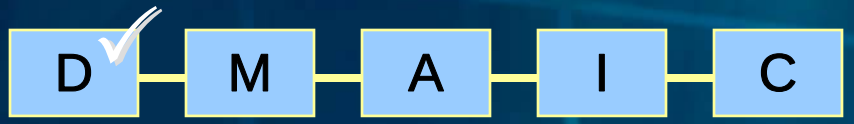
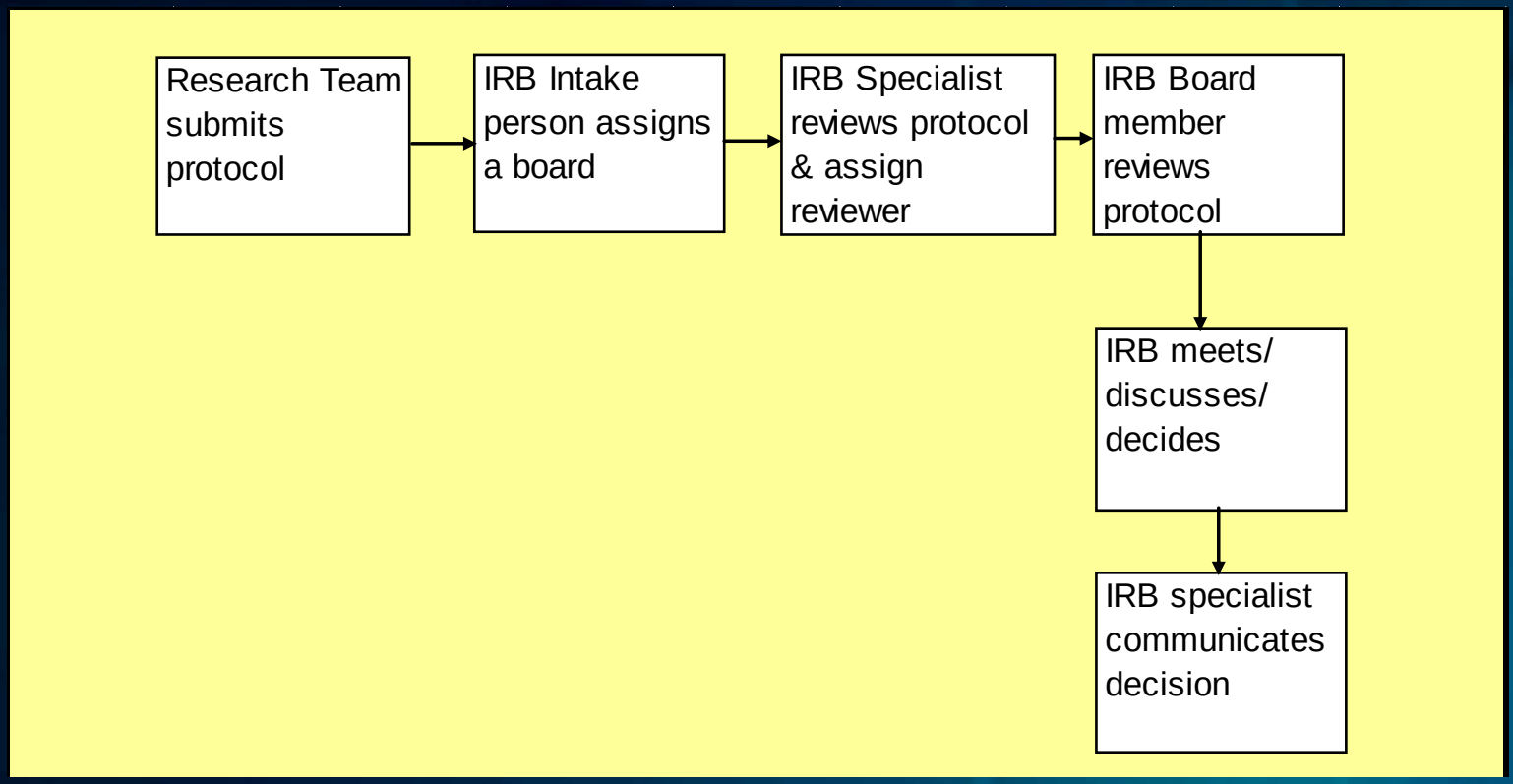




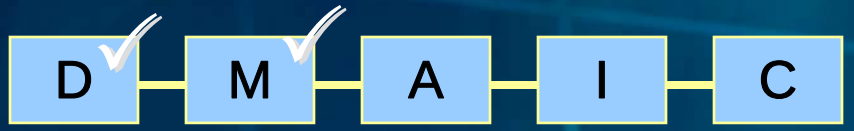
Potential Impact for the Customer

- Patients / Participants
  - Greater access to clinical trials
- Investigator
  - Improved satisfaction
- Industry
  - Improved satisfaction
- IRB
  - Enhanced compliance
  - Improved Morale
- Federal Agencies
  - Enhanced compliance

High Level Process Mapping



Measure



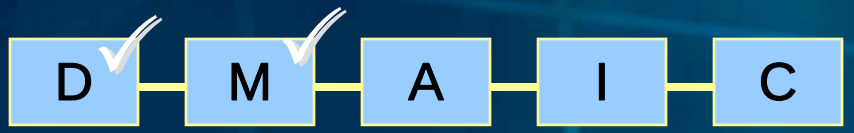
Define:

Measure:

Analyze:

Improve:

Control:

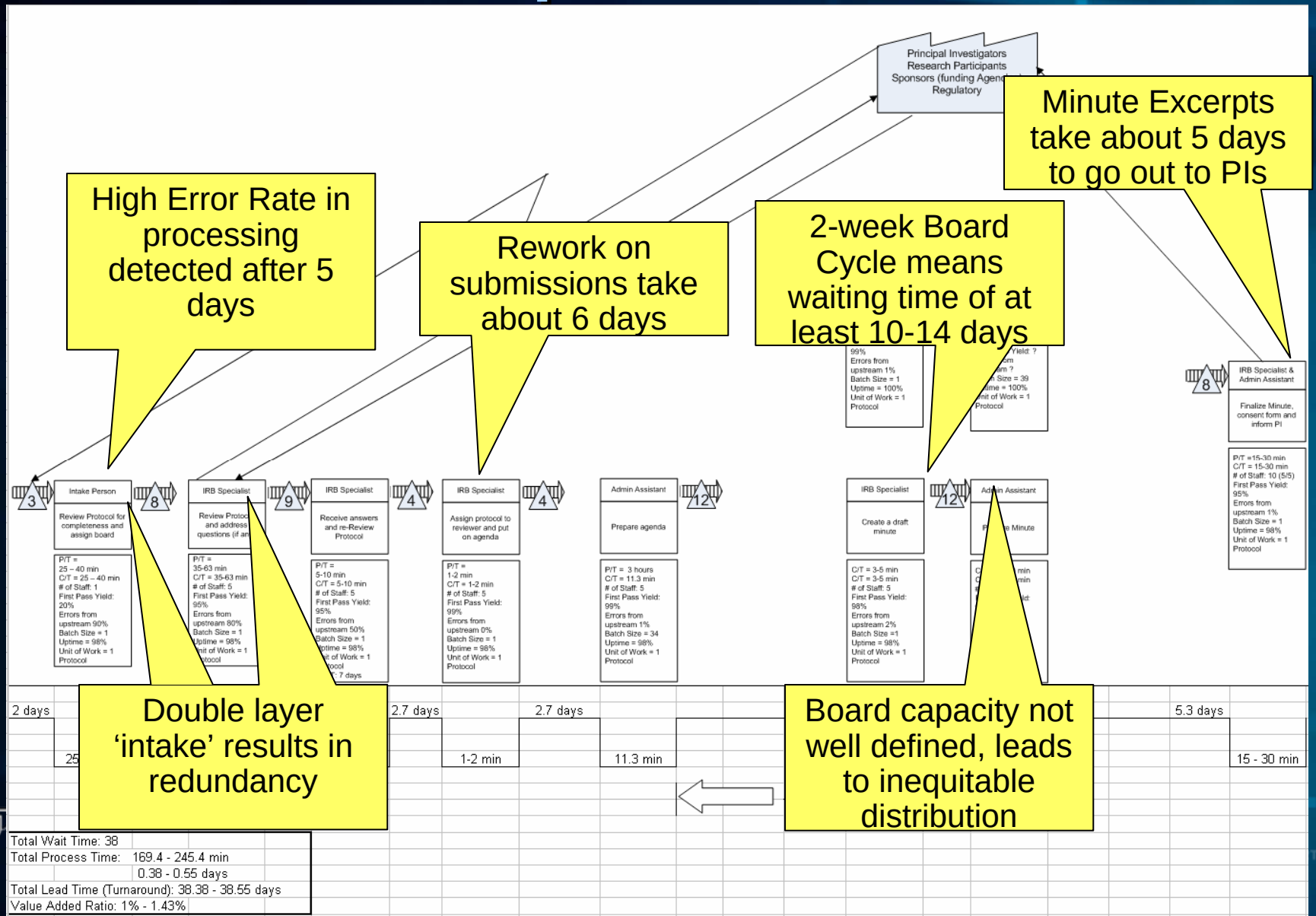


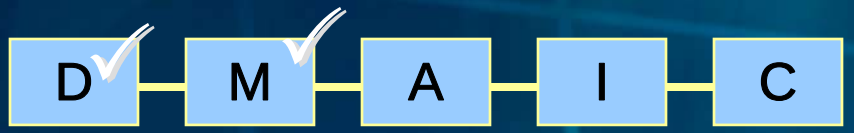
Value Stream Mapping Tool

- Examine the flow of information and work
- Locate the largest sources of waste
- Envision a less wasteful state
- Develop plans for future activities

Current State Value Stream Map

D M A I C





Results of the Current State Value Stream Map:

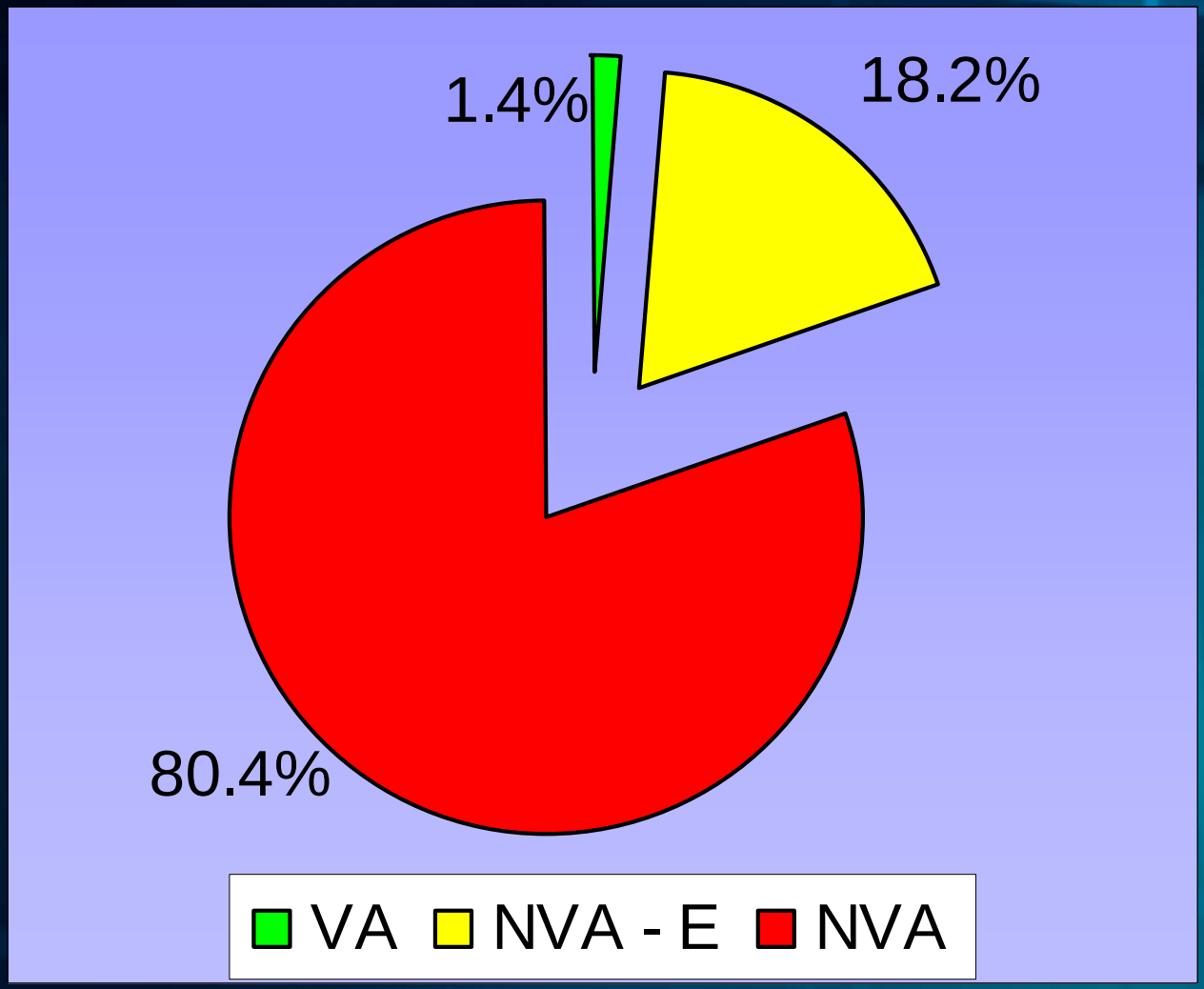
Total Wait Time: 38 days

Total Process Time: 169.4 - 245.4 min

0.38 - 0.55 days

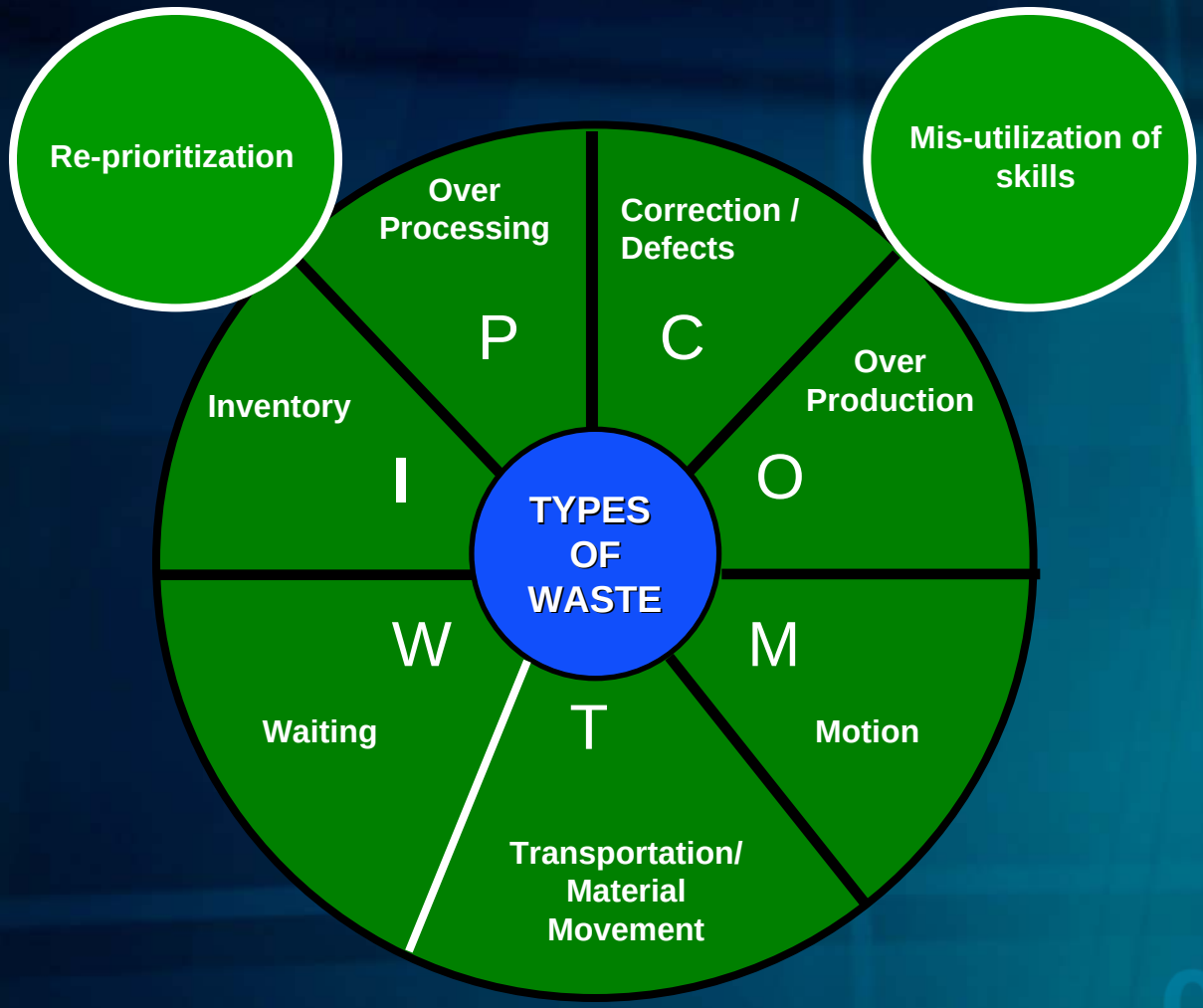
Total Lead Time (Turnaround): 38.38 - 38.55 days

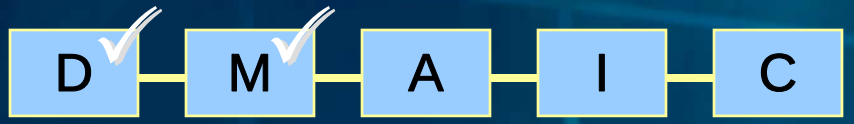
Value Added Ratio: 1% - 1.43%


1.4%
18.2%
80.4%
VA
NVA - E
NVA

IRB Wastes

D ✓ M ✓ A I C

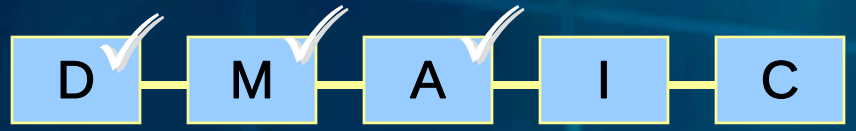


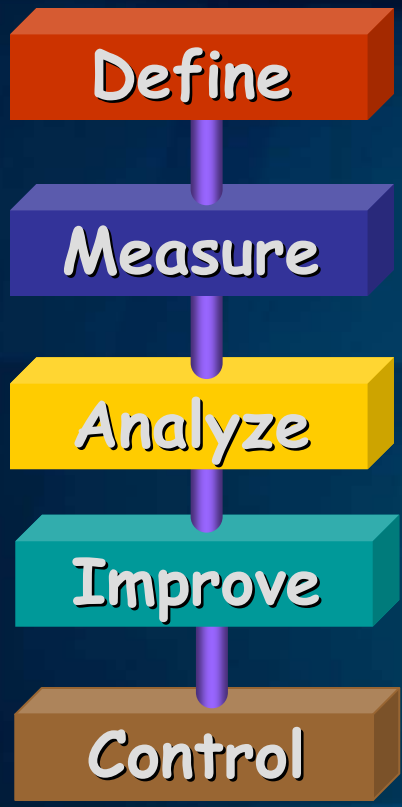


Data Collection

- # of IRB submissions
- # of submission outside the 21d target.
- Time to process a new submission
- Errors

Analyze





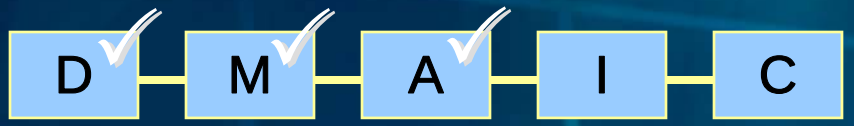
Define:

Measure:

Analyze:

Improve:

Control:



Analysis for New Submissions

- Working d/yr =

  365 - weekends- PTO= 230 d/ yr

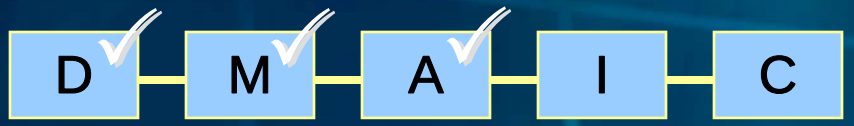
- Annual Demand of new full protocols for yr 2005 = 345
- Daily Demand =

  345/230= 1.5 protocols/day

- Work time a day =

  (8 hrs X 60 min) – (2 X 15 min Breaks) =

  450 minutes



Analysis for New Submissions

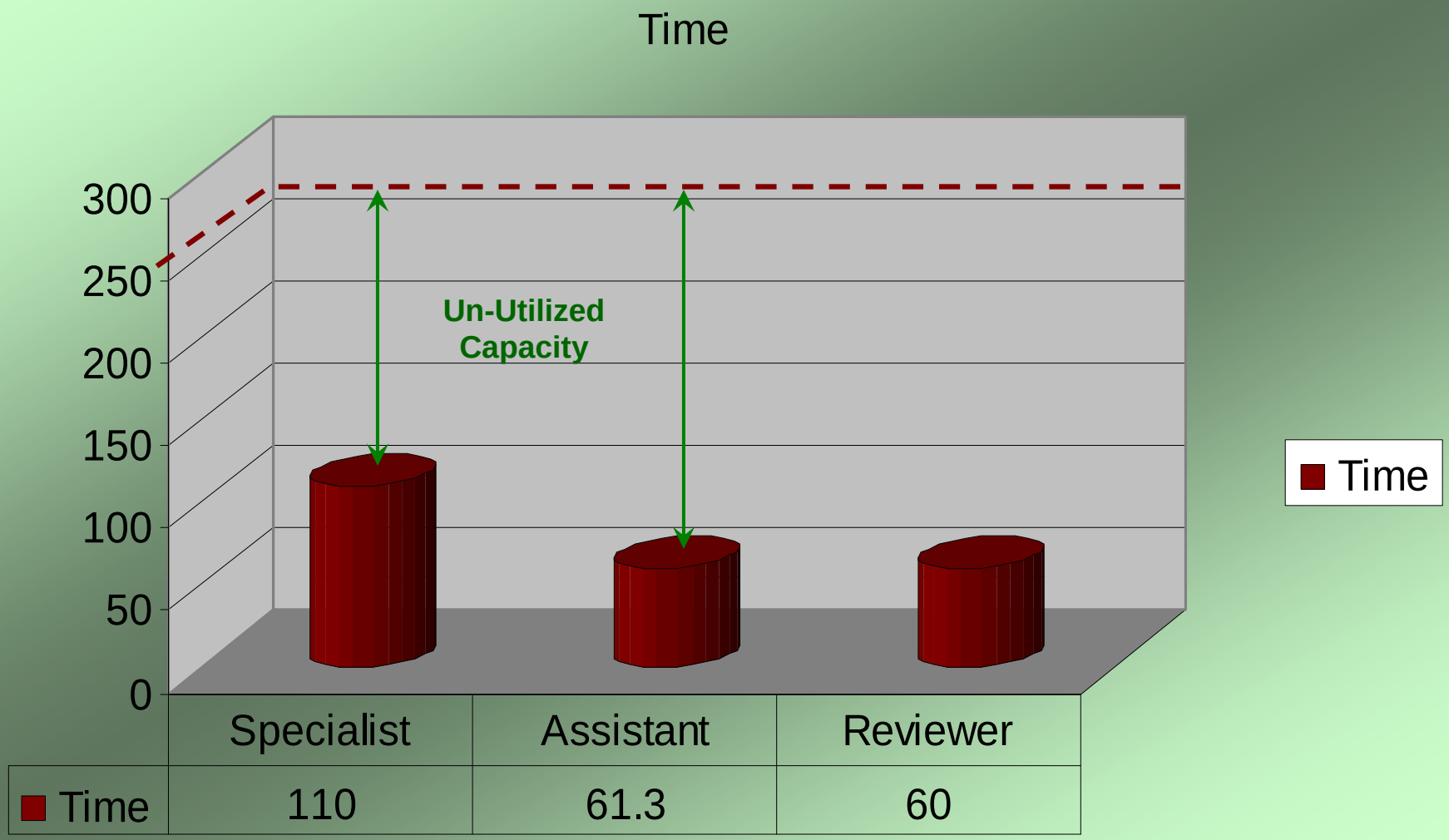
- **Takt* = (450 min/ day) / (1.5 protocols/ day) = 300 min/ protocol**
- **Variation adjusted Takt =**

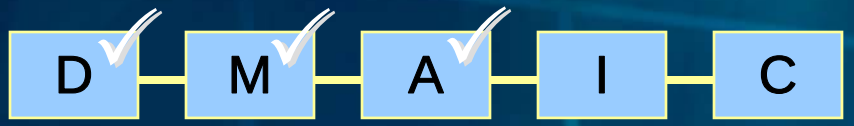
  (.85)X(300)= 255 min

*The pace (*German*)

Operator Chart

D M A I C



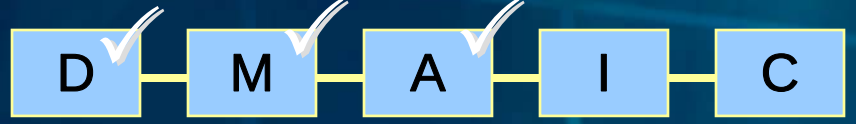


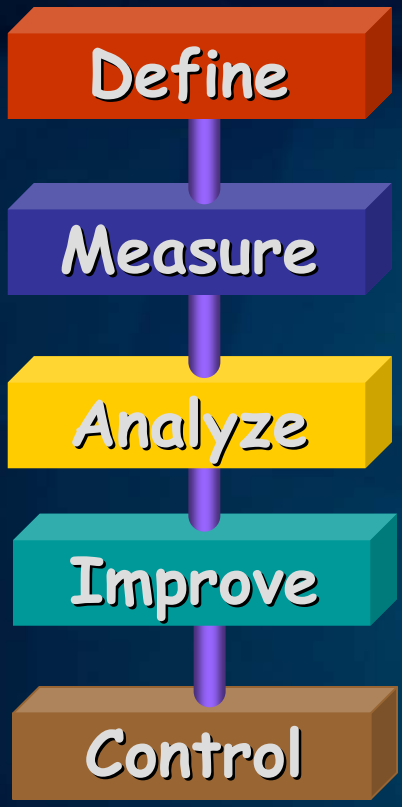
Analyze Phase

- Intake person has a very low yield (i.e. quality)
- IRB has more capacity than the demand
- RCA for errors required.

Conclusion: Opportunities for improvement

Improve





Define:

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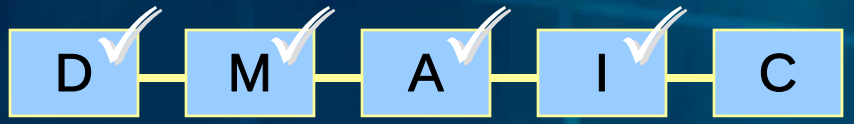
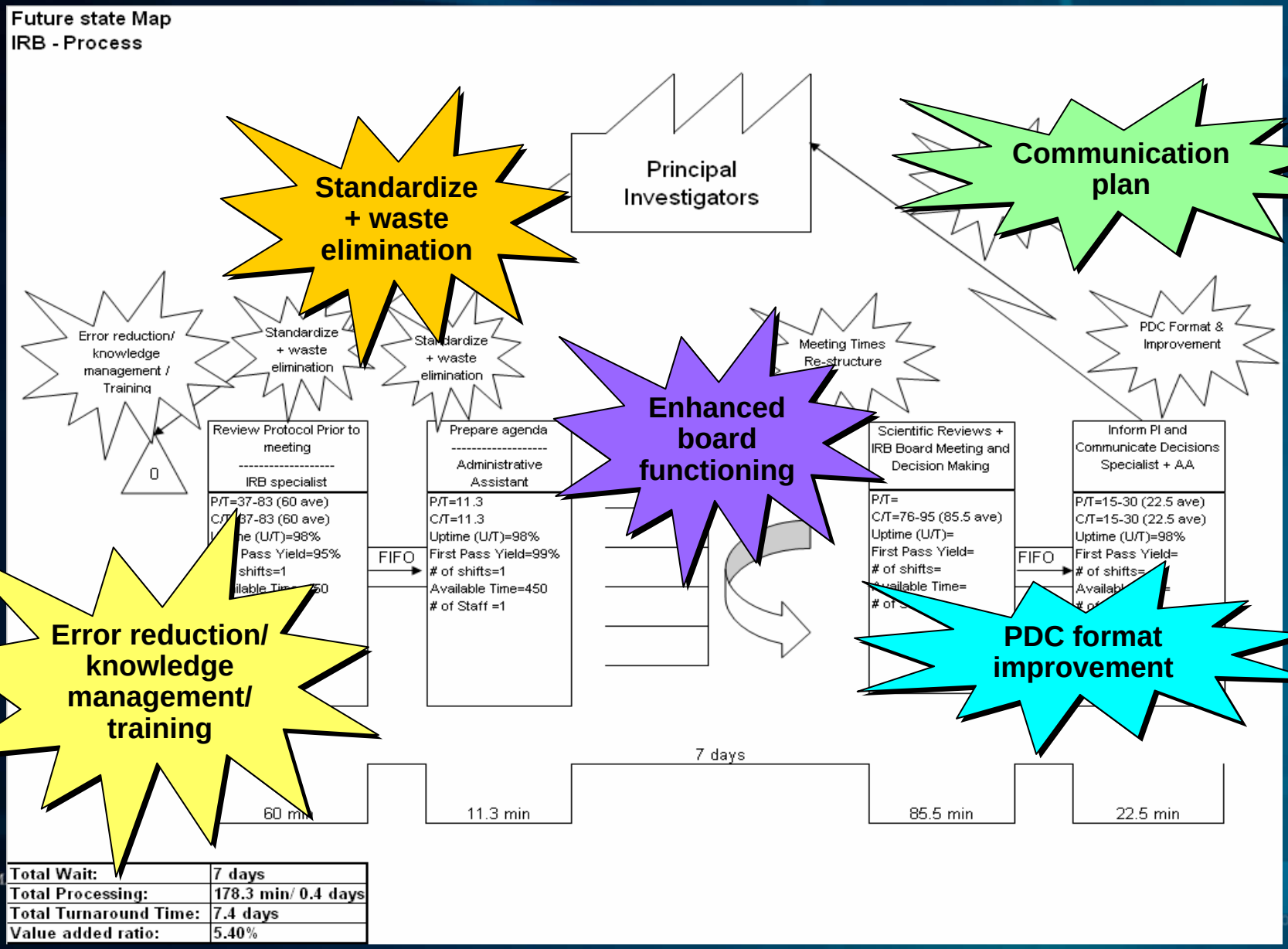


Brainstorm Improvements

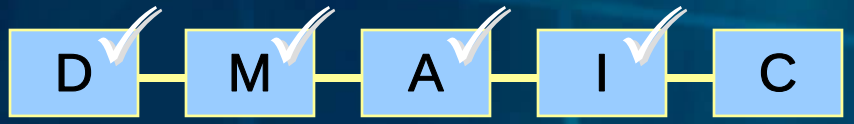
- Eliminate the Intake function
- IRB Specialist reviews 1st
- Standardize work elements.
- Mistake proofing to reduce errors.
- Communicate with the Research audience
- Continuously improve
  - Seek feedback from customers
  - Analyze data

Future State map

D ✓ M ✓ A ✓ I ✓ C



Total Wait:	7 days
Total Processing:	178.3 min/ 0.4 days
Total Turnaround Time:	7.4 days
Value added ratio:	5.40%



Future State map results

Total Wait:	7 days
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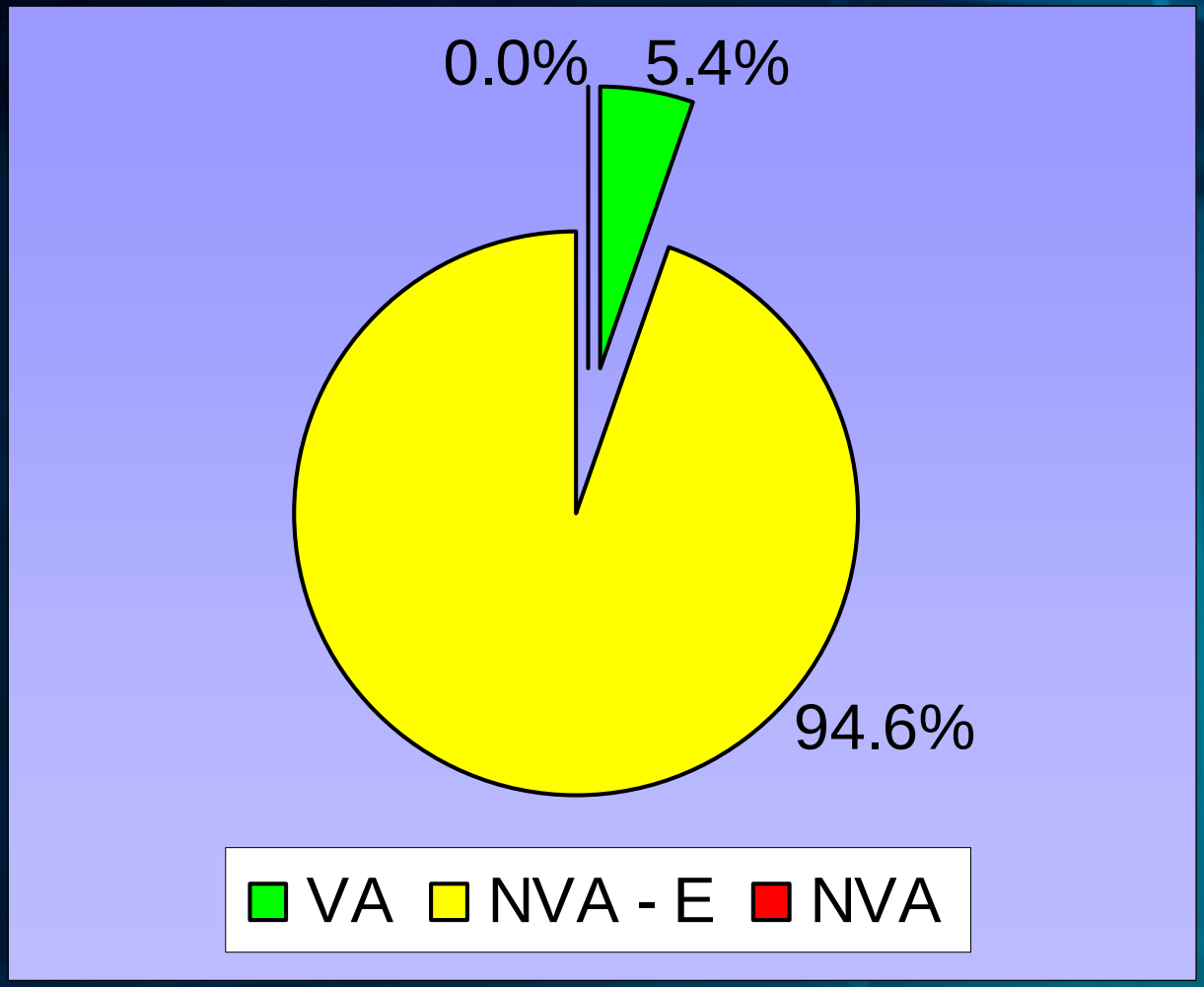
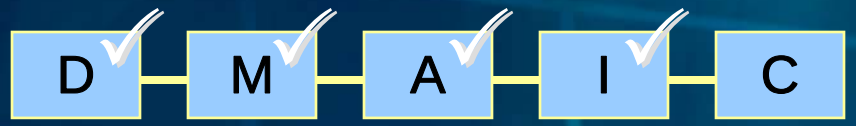
D M A I C

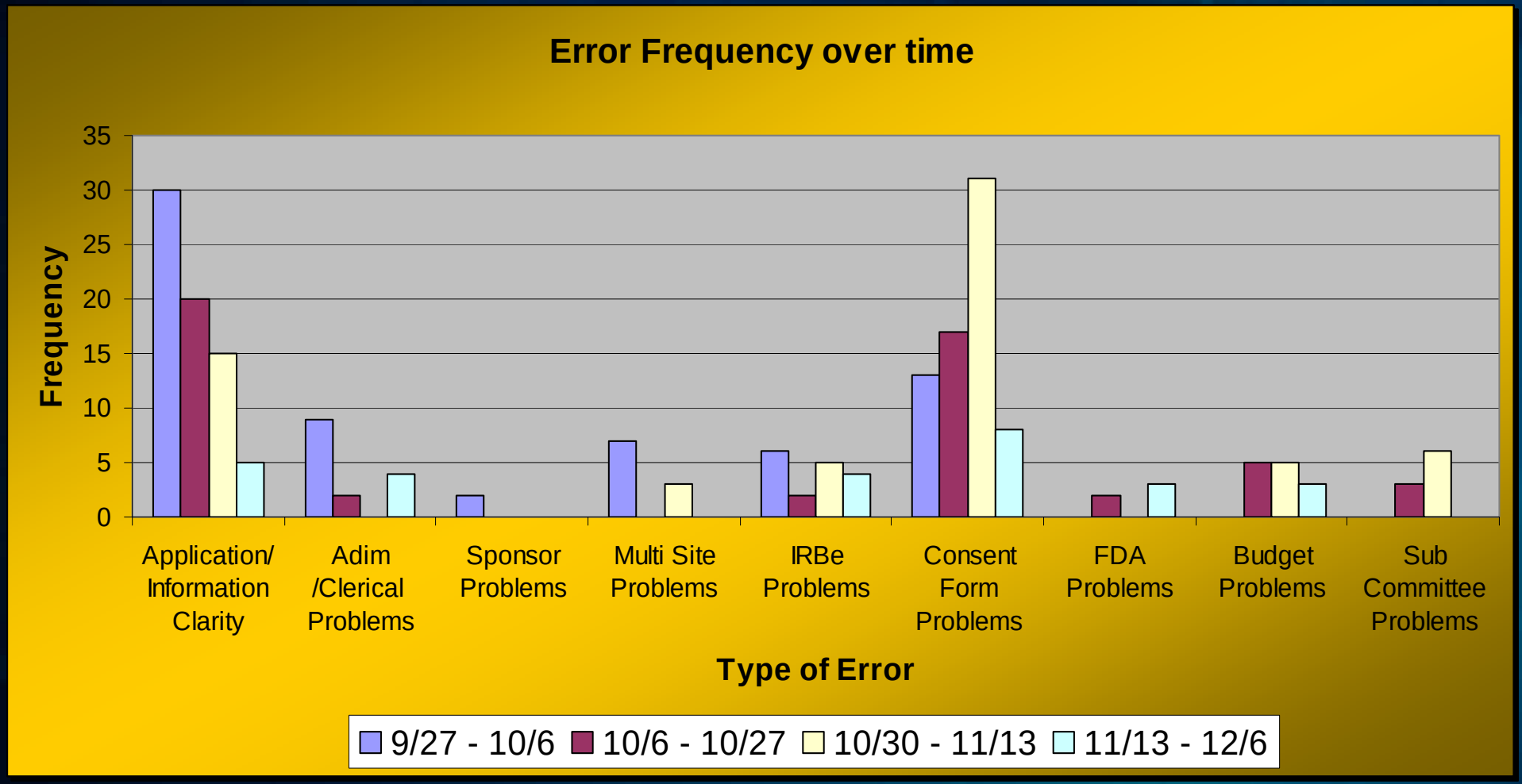




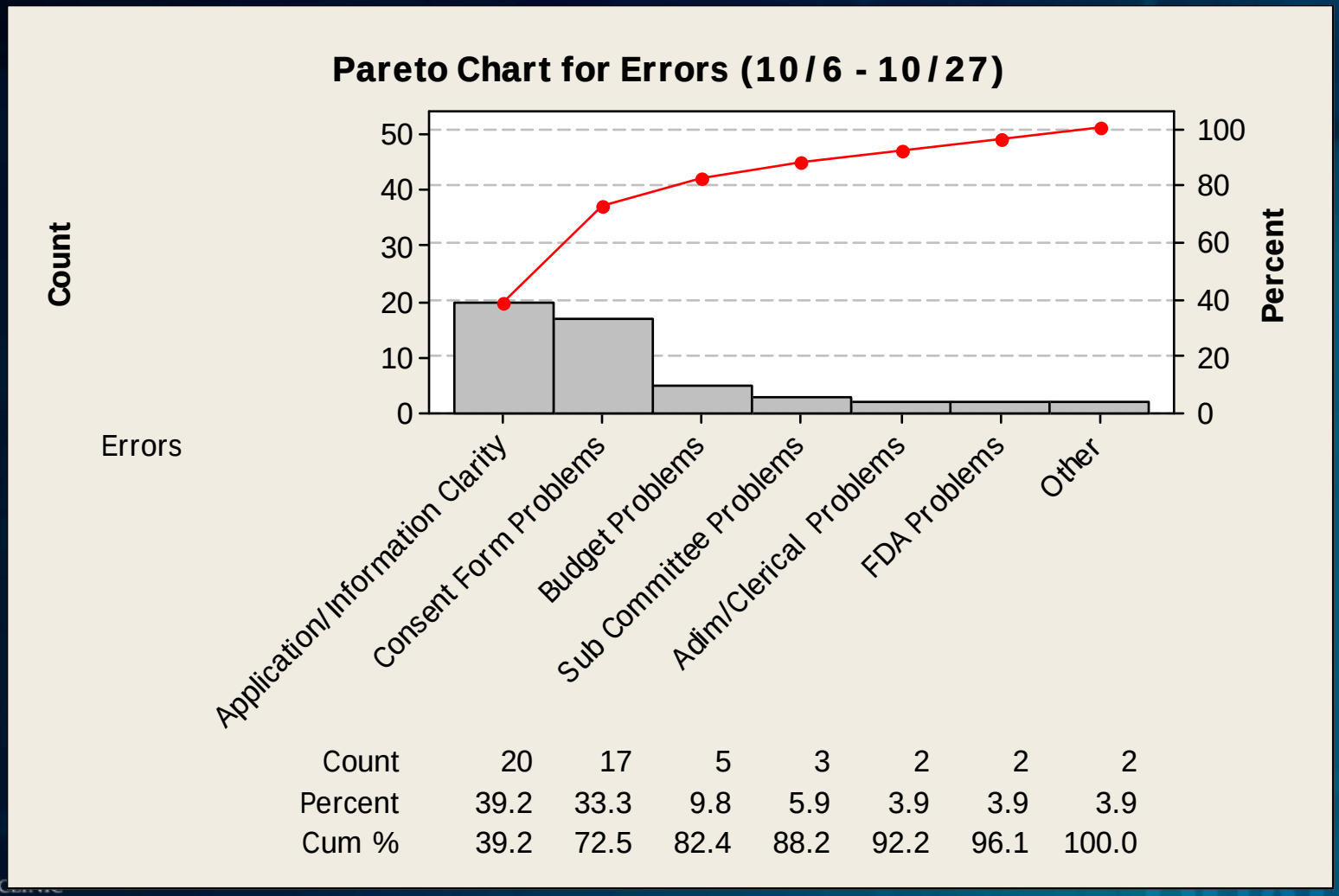
Validate Improvement – Compliance

D M A I C

Validate Improvements – Error Frequency



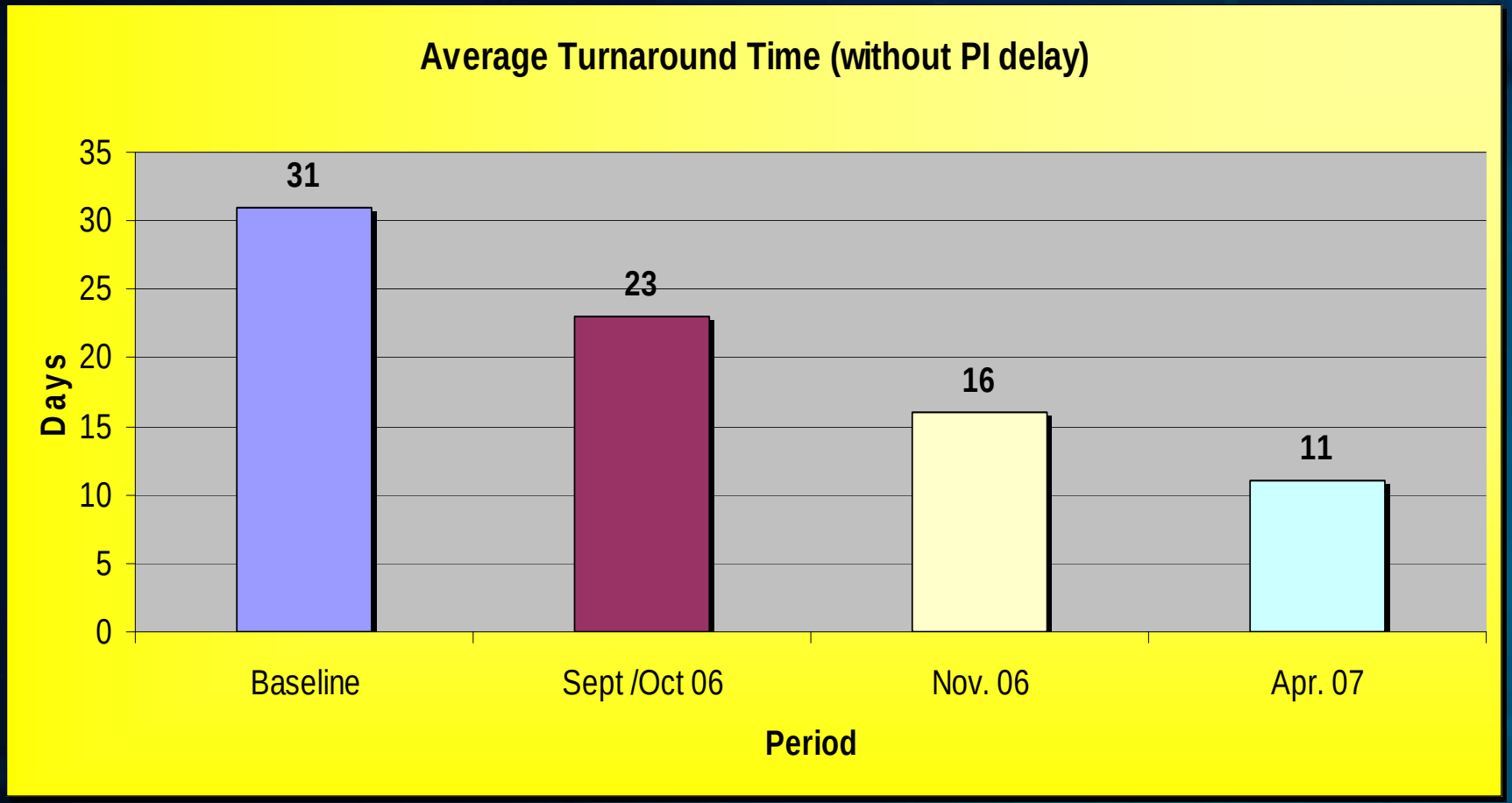
Pareto Chart for Errors

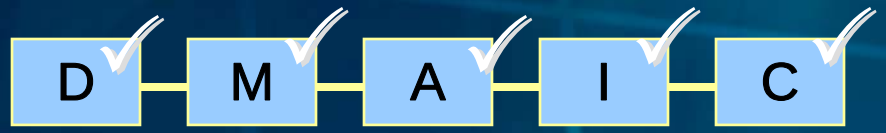


Count	20	17	5	3	2	2	2
Percent	39.2	33.3	9.8	5.9	3.9	3.9	3.9
Cum %	39.2	72.5	82.4	88.2	92.2	96.1	100.0

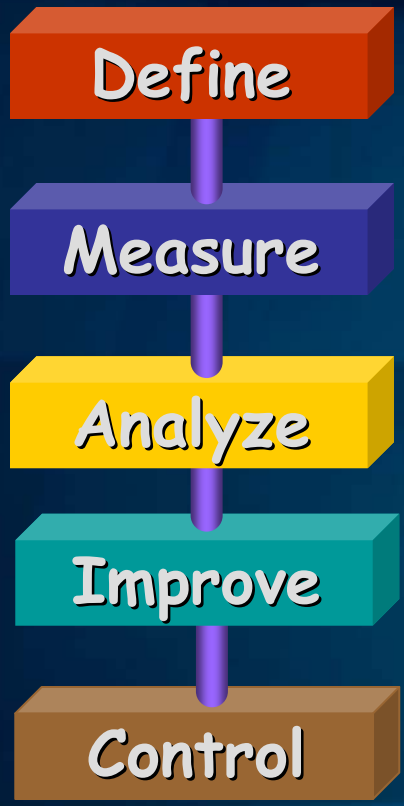
Average Days Turnaround of New Full Board Protocols

D M A I C





Control



Define:

Measure:

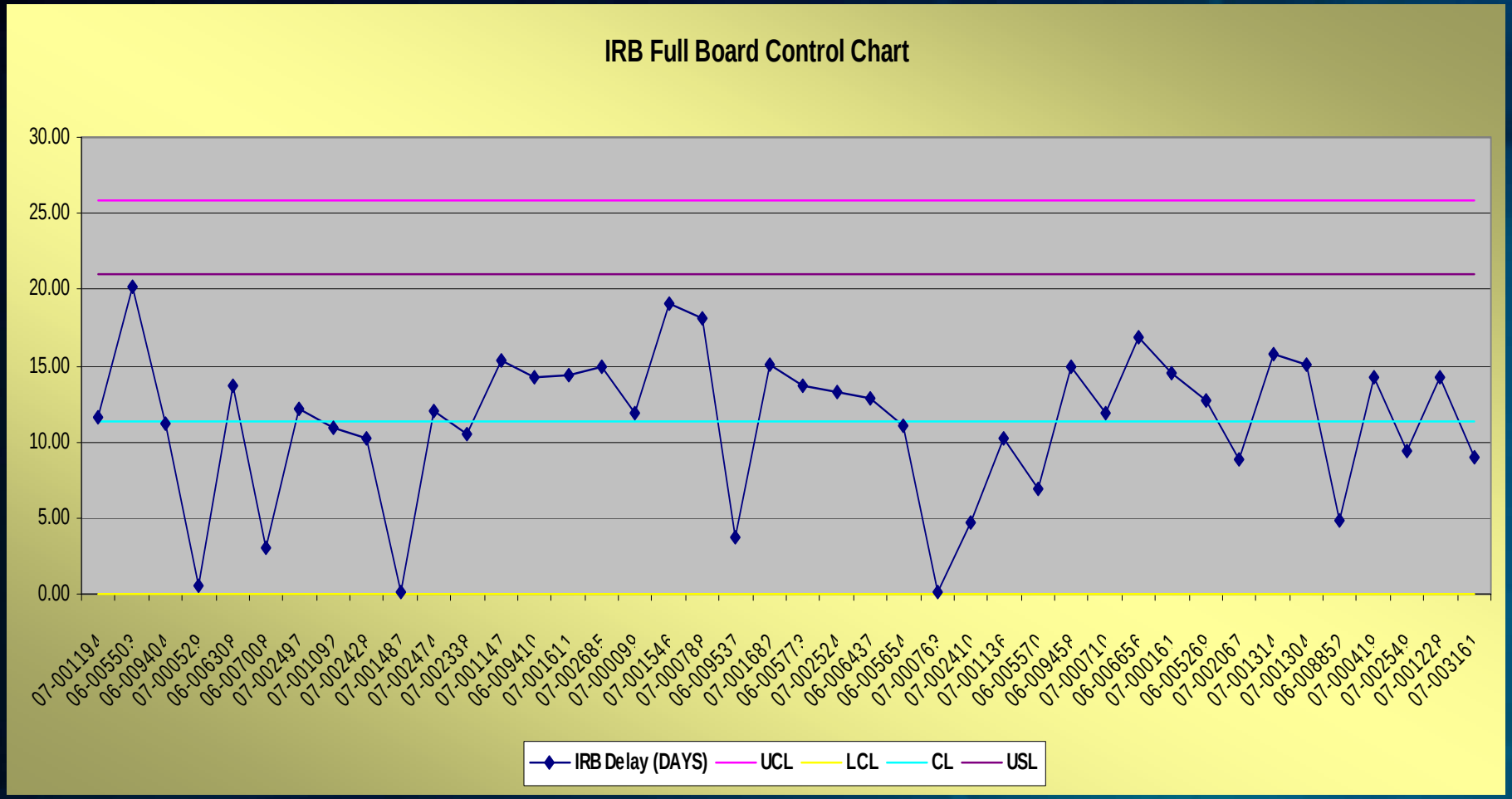
Analyze:

Improve:

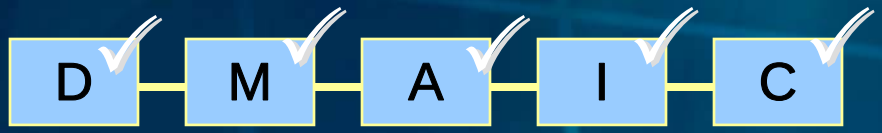
Control:

Control Charts

D M A I C



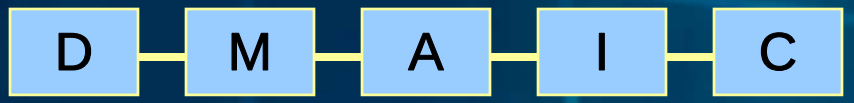
Control Phase



- Consistent and improved process
- Within control: Control Charts

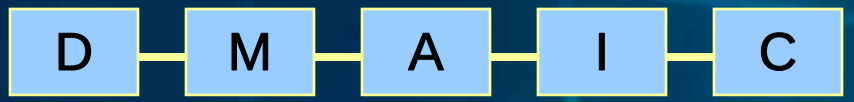
- Control plan
  - –Measurement System Assurance: Including monitor (Alerts) to ensure the process success.
  - –Reaction plan.

Lessons to share

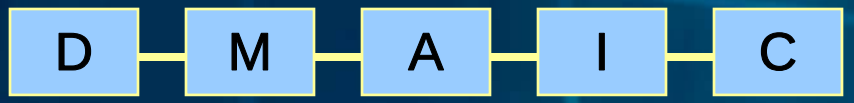


- DMAIC proved to be effective in Healthcare processes including administrative/ business processes.
- Research Administration, as a result launched 3 system-wide process improvement teams and established their own “Research Quality Office” recently.
- Other institutions benchmark with Mayo IRB

Lessons to share



- Staff resistance to change!
- Information Technology (IT) support
- Process owners commitment is critical to the success of the initiative.
- The right skills on the team.
- Customer and External effect.



Thank You.

Questions?