Knight Cardiovascular Institute Clinical Research

How we achieved the 60/60/60 Benchmark

DATE: March 6th PRESENTED BY: Beth Wilson, BS Clinical Research Manager

Who we are

- 21 Clinical Research Staff
  - 15 Coordinators, a research nurse, and a research APP
  - Operations Manager, Finance Manager, and Regulatory/Start-Up Specialist
- ~100 trials currently housed within the team

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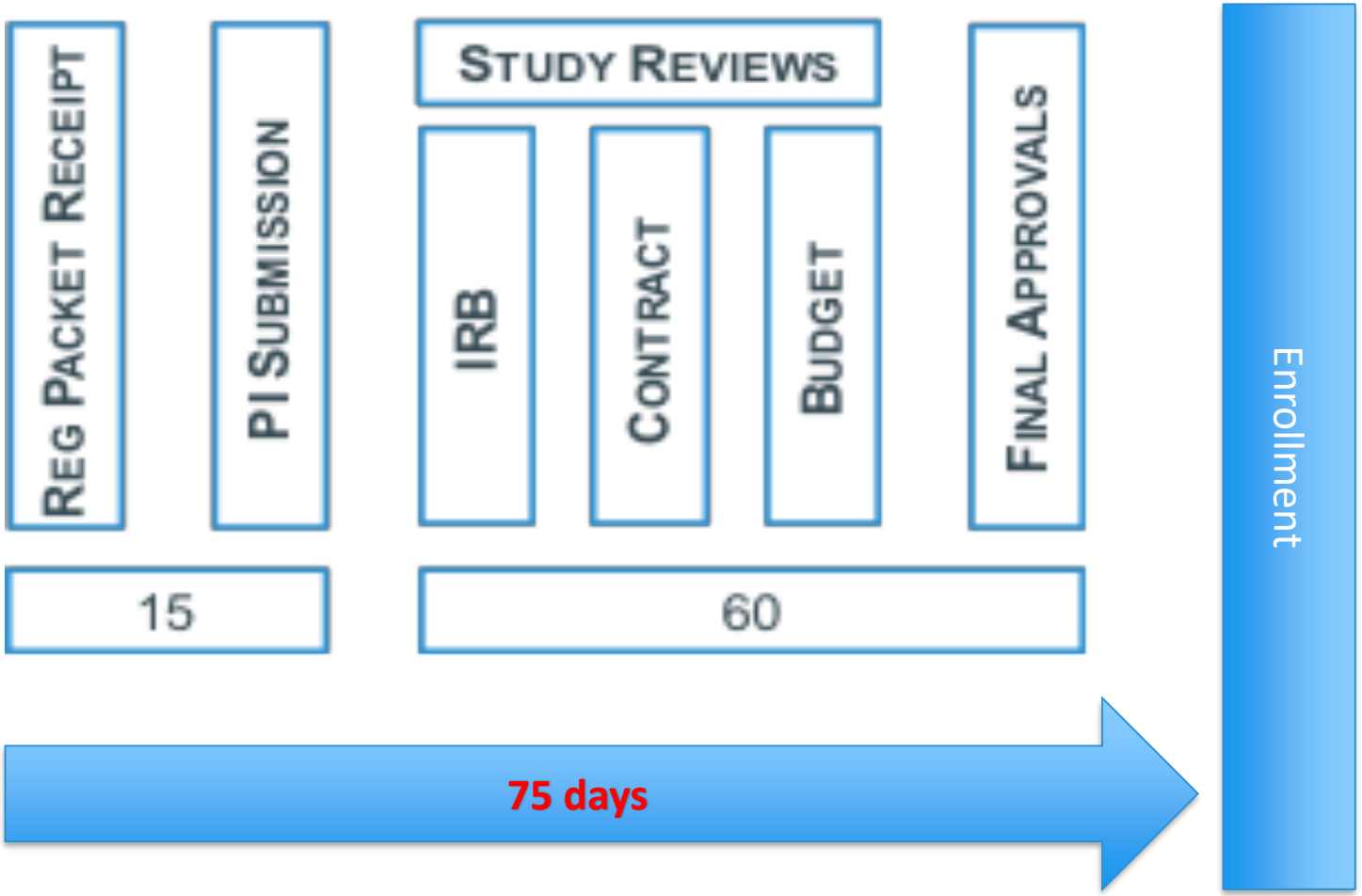
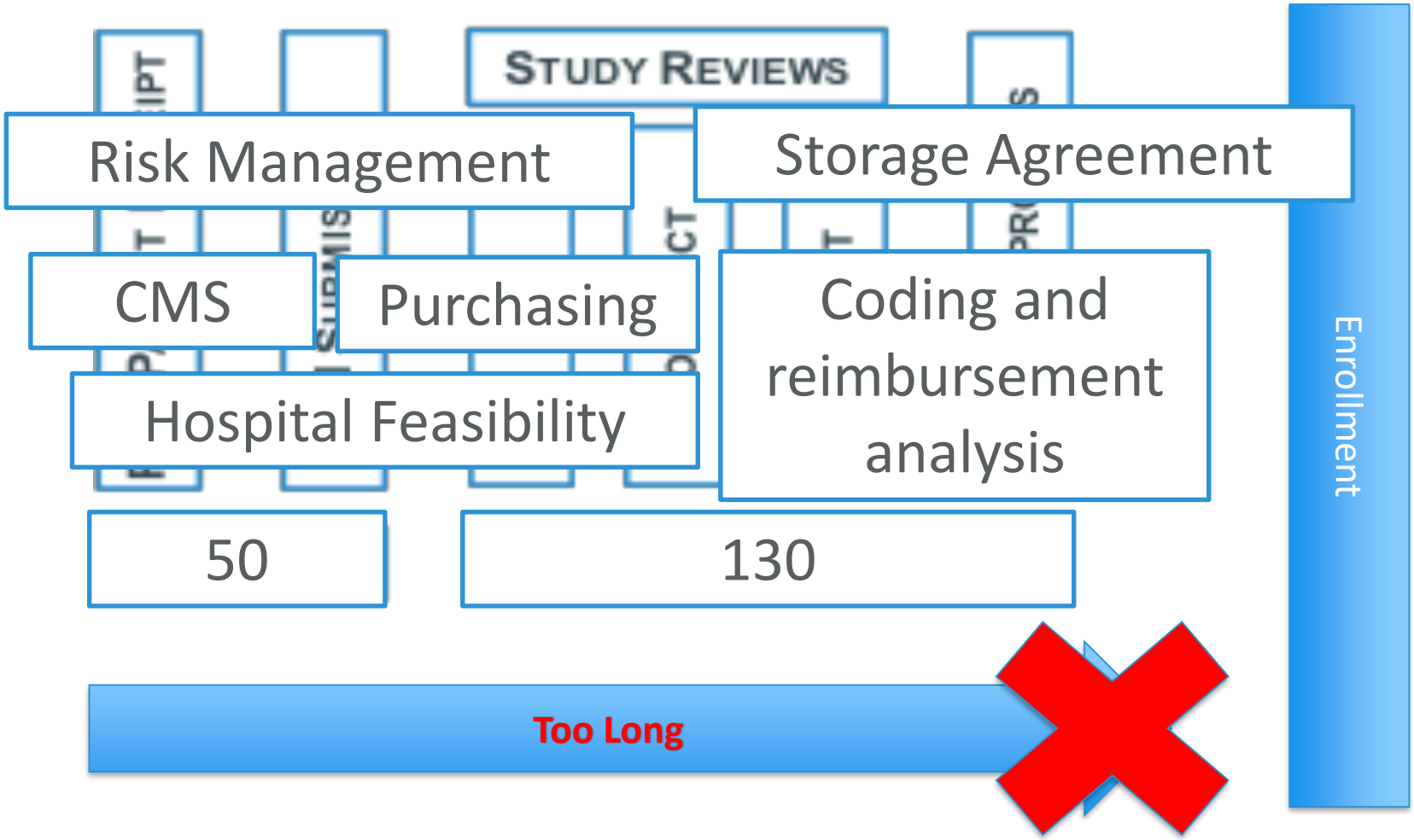
OHSU Approval Process- 2016



The 280 Day Study

OHSU

The 280 Day Study



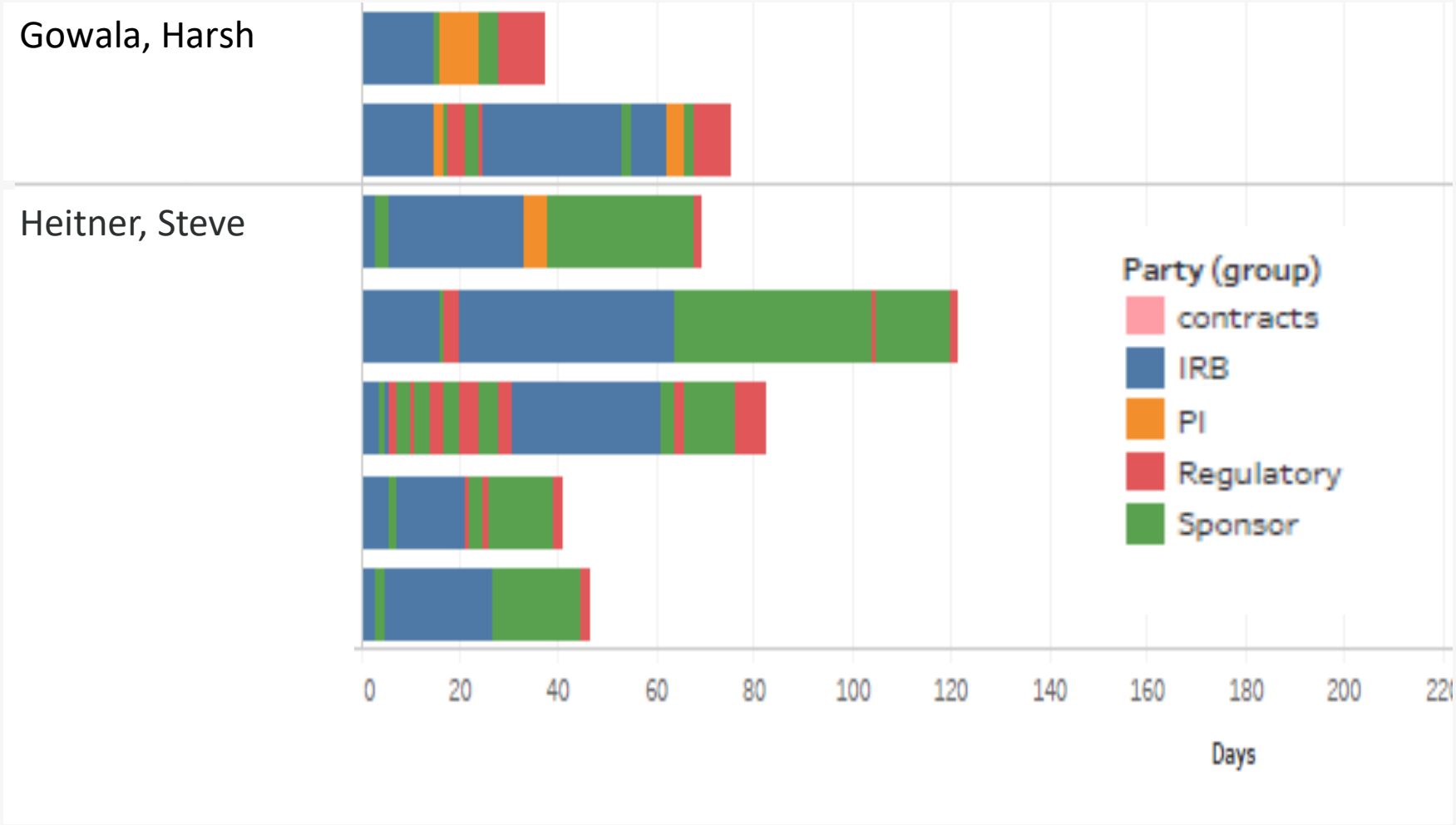
Lessons Learned

- Institution was not built to support device trials
- Development of new approval processes needed
- Stakeholders still needed to be verified
- OHSU needed a driver

Active Engagement

- Prospective reporting metrics
  - Internal deadlines for approvals and expectations of sponsor turnaround
  - Weekly PI meetings/Status Check-In
  - PI to sponsor relationships

Start-Up Timeline Reporting



Device Committee

- Identify institution stake holders
- Eliminate artificial bottlenecks
- Develop efficient processes for necessary internal approvals
- Allocate Master Contract Support for all device sponsors

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Round 2 in 2018
New Sponsor, New Opportunity

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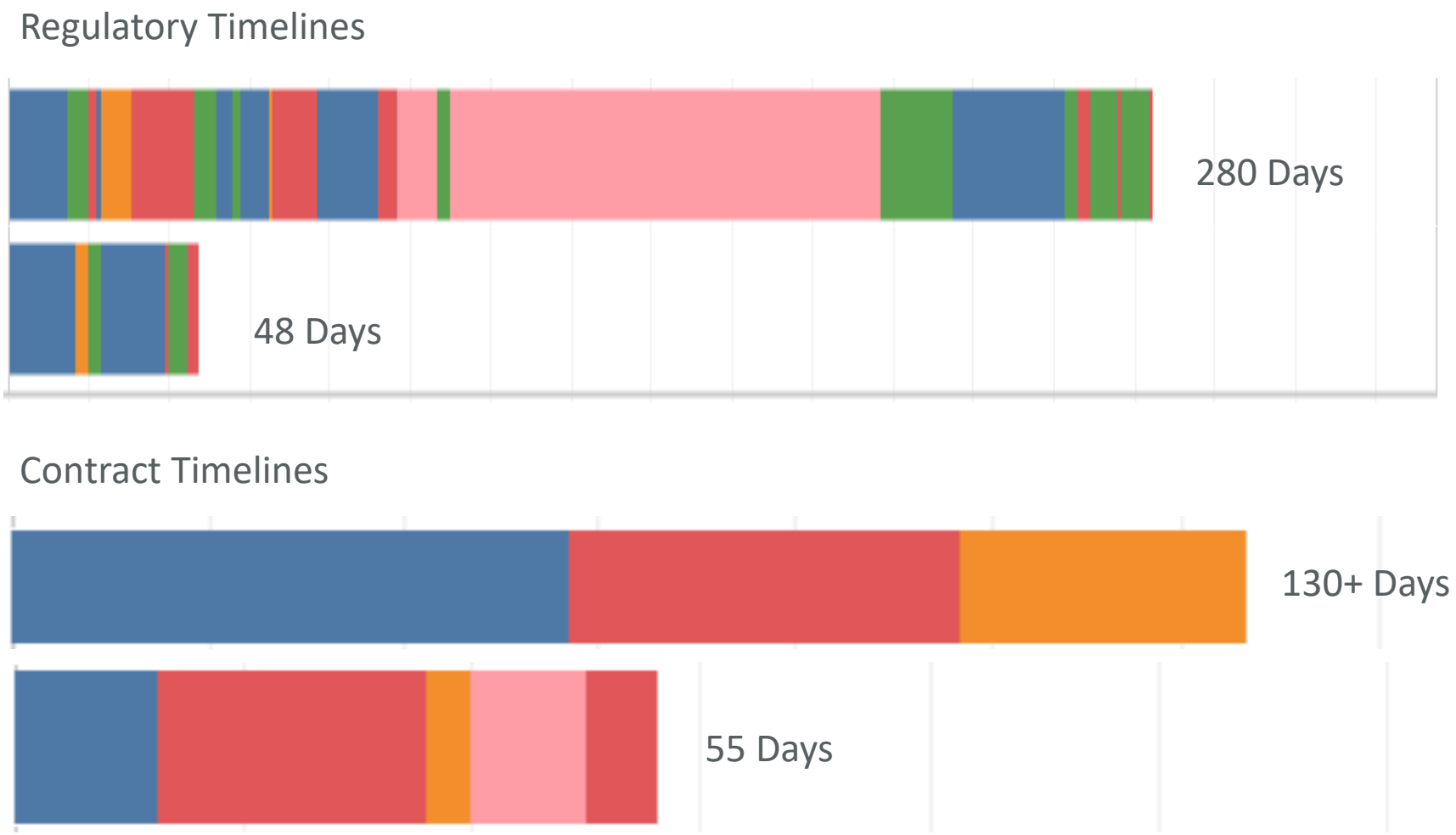
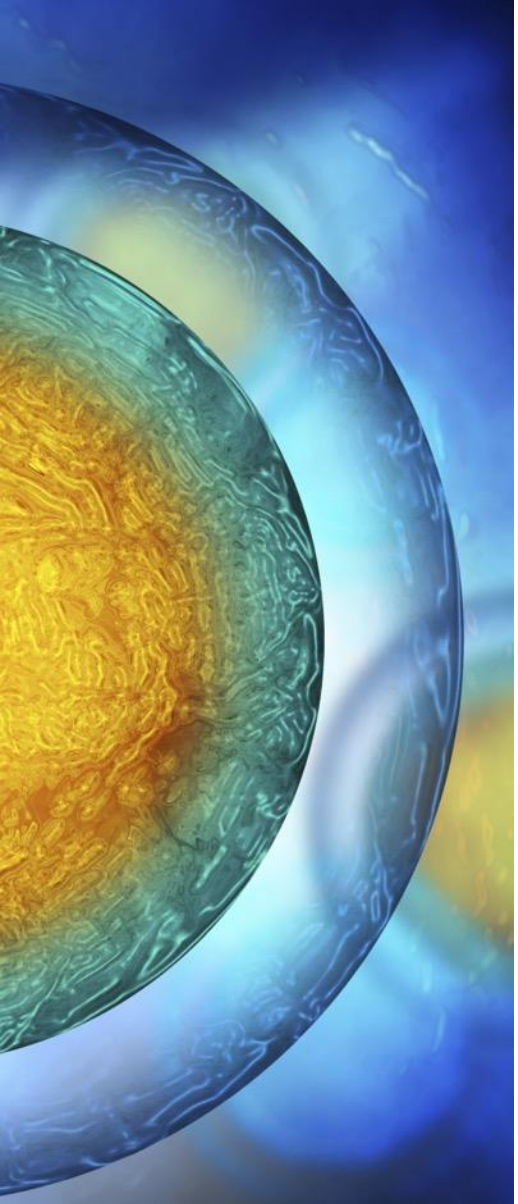
The 280 Day vs. New Study





Key Considerations

- Identify all stakeholders involved in approval processes for your institution AND ENGAGE THEM.
- Approach relationship with sponsor as a partnership
- Master Contracts
- Active facilitation through approval process

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