Study Start-Up Metrics

FRED HUTCH / UNIVERSITY OF WASHINGTON
CANCER CONSORTIUM

Jiwon Kang
jwkang@seattlecca.org
Phase 1 Oncology Clinical Trials Program
https://www.seattlecca.org/program/phase1/about

Problem

Start-up delays impede the success of trials by reducing enrollment and site performance and increasing administrative costs
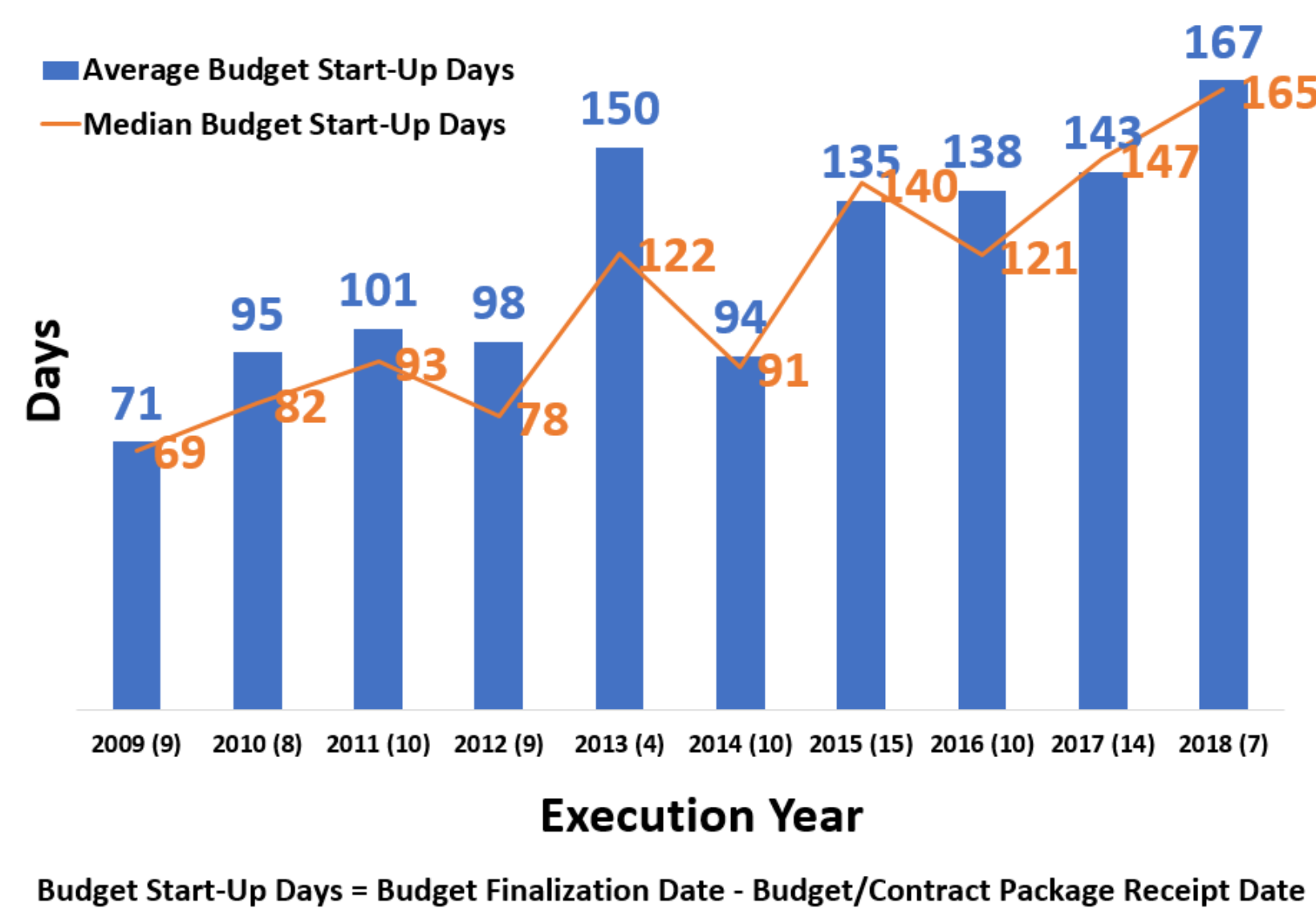
Goals

- Remain competitive as a site
- Assess the Program's current start-up capabilities
- Identify causes of start-up delay
- Prevent start-up delays
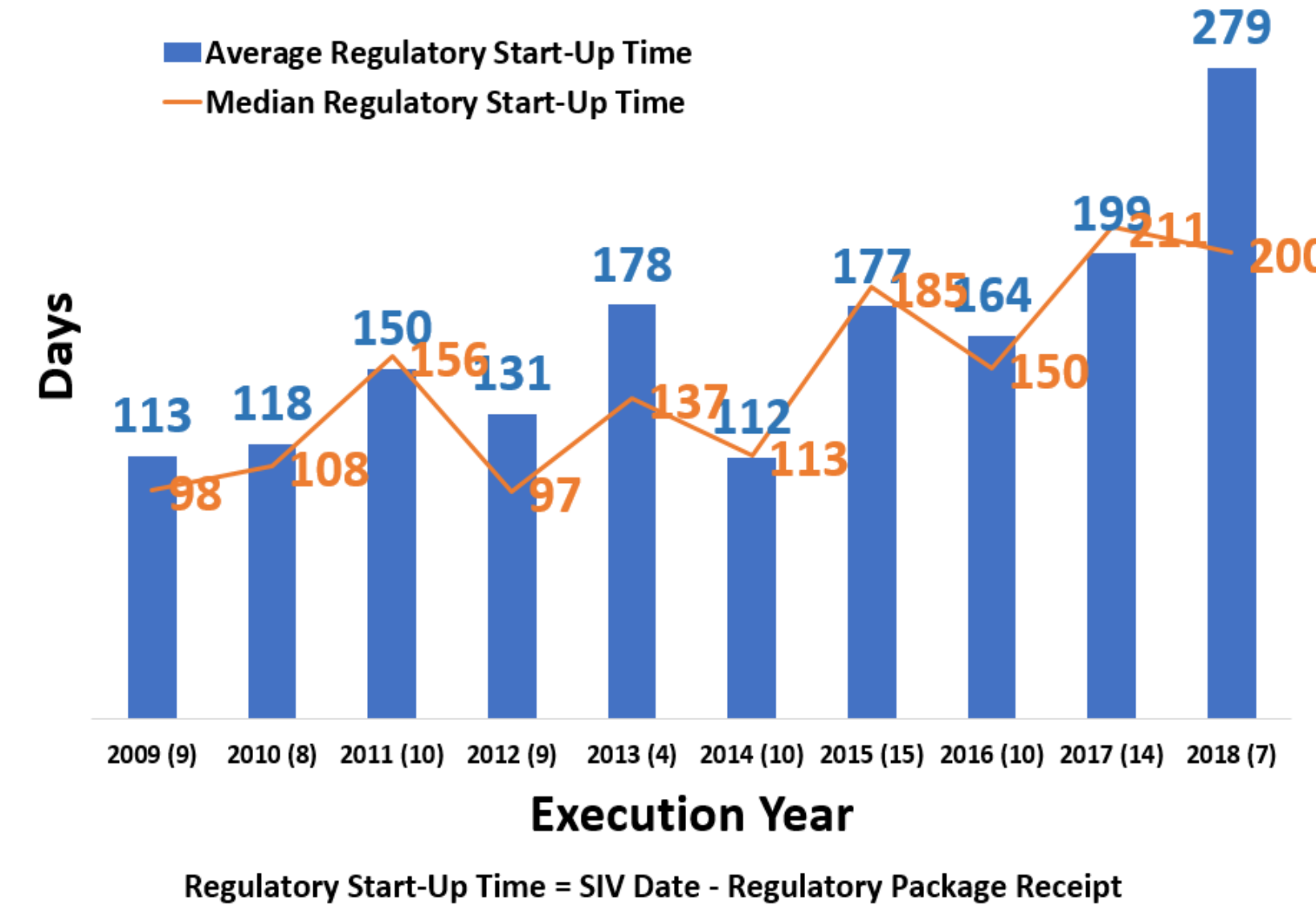- Provide feedback to stakeholders

Project Methods

The Program built a database on start-up timelines of 98 sponsor-initiated trials in the past 10 years. Analysis was completed on 96 studies with available data and focused on 4 areas of study start-up: (1) Budget negotiation, (2) Regulatory, (3) Contract execution and (4) Site implementation visit (SIV). Analysis was done on the following types of data:

- Budget/contract receipt date
- Budget finalization date
- Regulatory package receipt date
- Contract execution dates by sponsor and UW
- SIV date

Budget Start-Up Time

Budget Start-Up Days = Budget Finalization Date - Budget/Contract Package Receipt Date

Regulatory Start-Up Time

Regulatory Start-Up Time = SIV Date - Regulatory Package Receipt
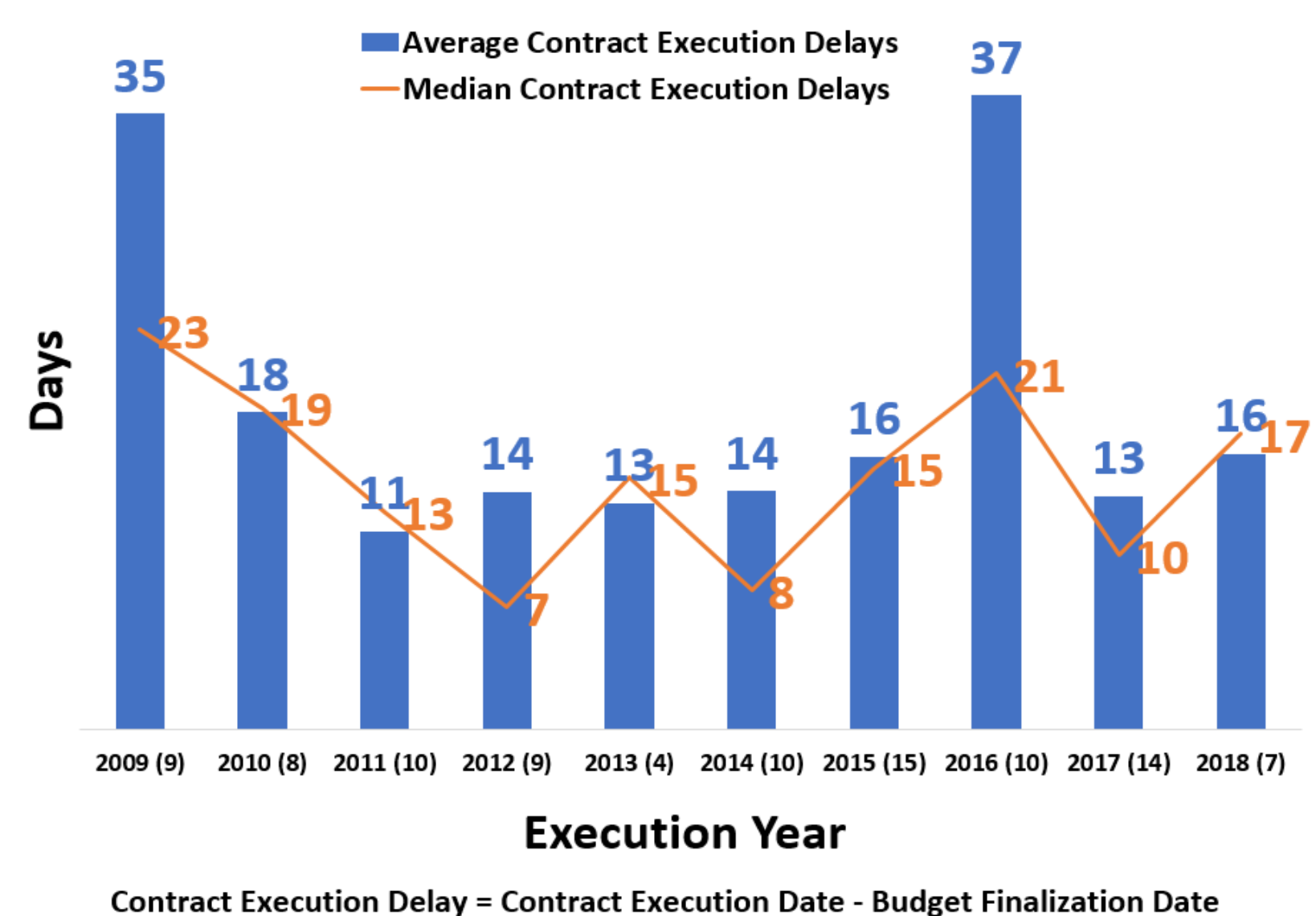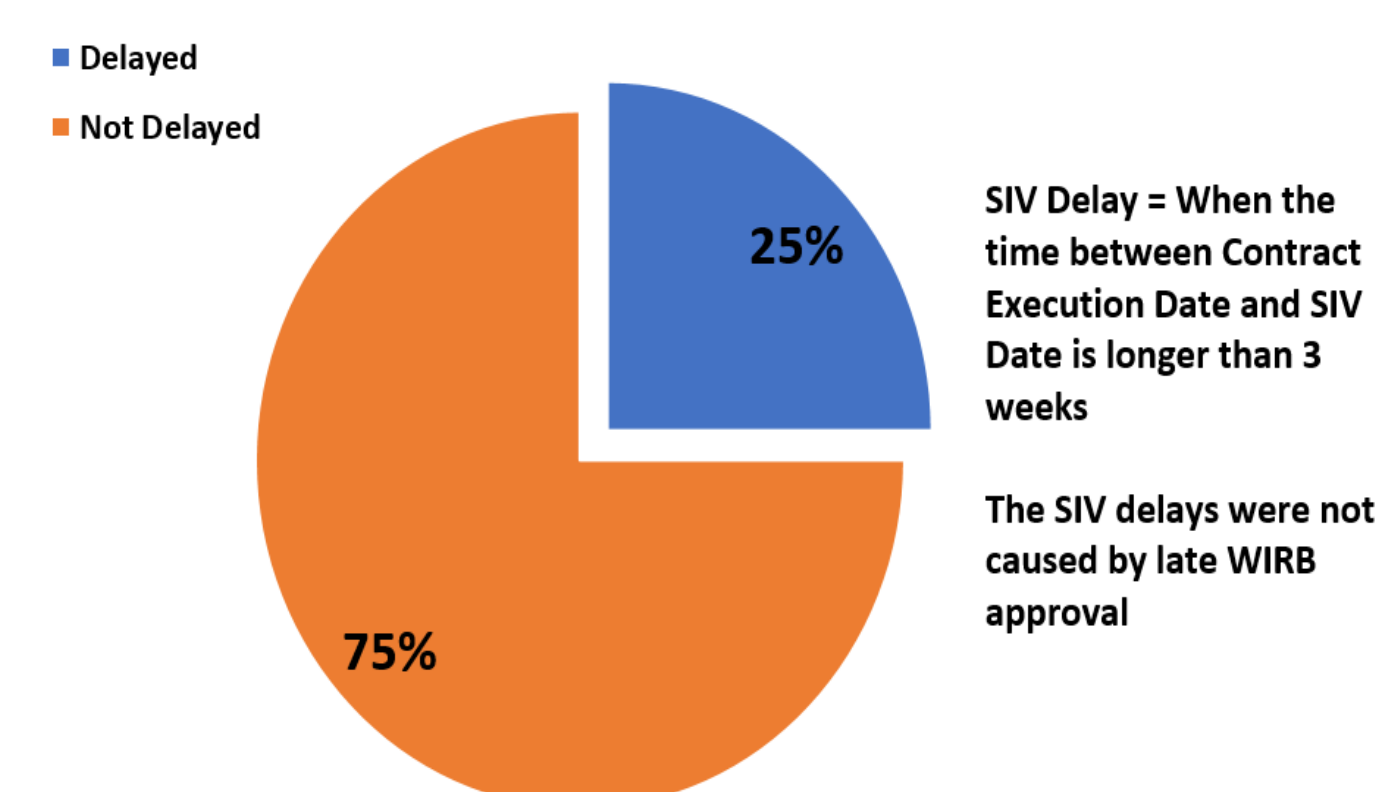
Best Practice

Implement a metric-driven tracking system to identify and mitigate delays that impact study start-up in 4 critical areas:

- ➢ Budgets
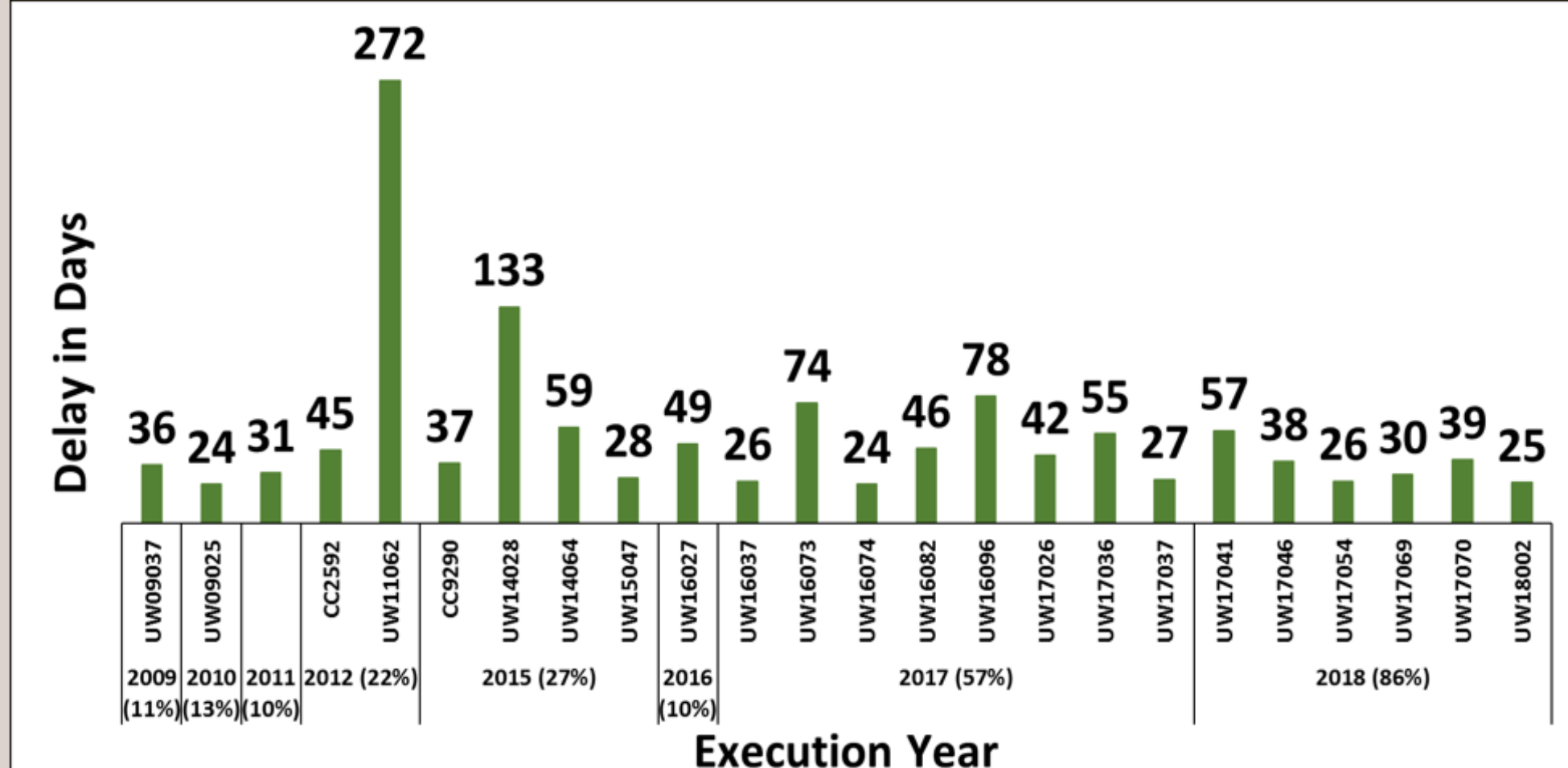- ➢ Regulatory
- ➢ Contracts
- ➢ Site Implementation Visits (SIV)

Contract Execution Delays

Contract Execution Delay = Contract Execution Date - Budget Finalization Date

% of Delays Caused by SIV

SIV Delay = When the time between Contract Execution Date and SIV Date is longer than 3 weeks

The SIV delays were not caused by late WIRB approval

SIV Delays

Disclosure: Some of the delays caused by administrative holds specifically due to sponsors were subtracted from the start-up timelines of 9 studies

Causes of Delay

Institutional Factors

- System glitches
- Introduction of new stakeholders that participate in start-up
- Organizational process changes

Sponsor Factors

- Administrative holds placed by sponsors
- Change of study designs/inclusion criteria
- Mergers and acquisitions between sponsors
- High volume of protocol amendments

Internal Factors

- SIV scheduling
- Internal decision making
- Staff transitions

Prevention Strategies

- Schedule SIVs in a timely manner (within 3 weeks of contract execution)
- Have an effective, consistent communication with PIs to ensure continued interest in studies in pipeline
- Create a robust transition plan in case of staff turnover