



MCC Lab Metrics Case Study

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ABBOTT LABORATORIES



Metric	Category	Metric Title
1	General Operations	Project management turnover
2	Protocol Initiation	Percentage first supplies shipped on time to the first site for first patient
3	Site Initiation	Percentage first supplies shipped on time for all sites (all regions)
4	Data Cleaning	Percentage of queries from central laboratory to site based upon requisitions received
5	Data Cleaning	Average turnaround for resolution of queries from central laboratory to site
6	Site Support Services	Percentage of queries from site to central laboratory based upon requisitions received
7	Site Support Services	Average turnaround time on queries from site to central laboratory

Metric	Category	Metric Title
8	Safety	Percentage of panics that had both 1st attempt made and were successfully communicated to the sites within the defined turn around times
9	Laboratory Operations	Percentage specific test(s) reported within expected turnaround time
10	Laboratory Operations	Percentage tests not reportable
11	Data Management	Percentage on time accepted file transfers
12	Financial Management	Plan, Forecast and Actual Financial Report
13	Financial Management	Comparison of budgeted and actual transportation costs by region and/or country
14	Quality Assurance	Percentage of audit findings closed within sponsor and central laboratory agreed upon timeframe

Financial Management Metric

Comparison of budgeted and actual transportation costs by region and/or country

Minimum: The transportation costs will be added by region and/or country to each of the segments.

Additional analysis on a “for cause” basis:

The transportation costs could be further defined by type (e.g. ambient, frozen and combination).

- % Sites Outside of US/Canada
- Location of Sites
 - Gateway City vs. Outlying City
- Length of Enrollment
- Plan for Shipment of Outbound supplies
 - Use of a central receiving site Ex-US

- Plan for shipping inbound supplies
 - # subjects in each package
- Type of Packaging needed
 - Ambient Shipper
 - Frozen (Dry Ice) Shipper
 - Combo Shippers

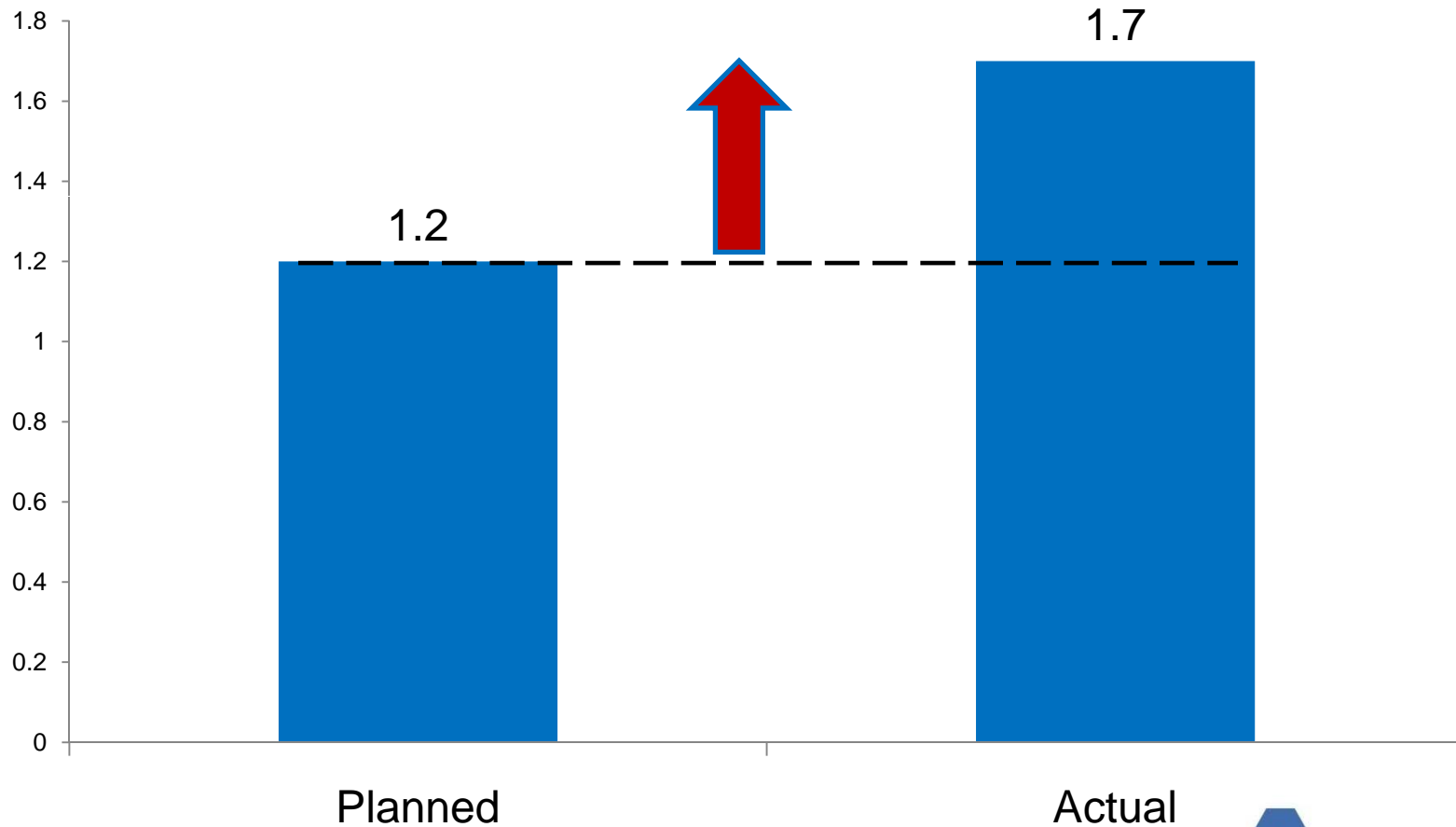
- In a large Global Study, the transportation budget is often >25% of the Central Laboratory Budget.
- The Initial CL transportation proposal can be done in many ways.
- At the time of Budget estimation, study site locations are often not known.
- How do we manage these Pass Through expenses?

- Estimate inbound costs conservatively – 1 subject per package for inbound shipments
- Use a gateway city to estimate site costs if the exact location is unknown
- Estimate outbound costs with no built in excess
- Use packaging as recommended by CL

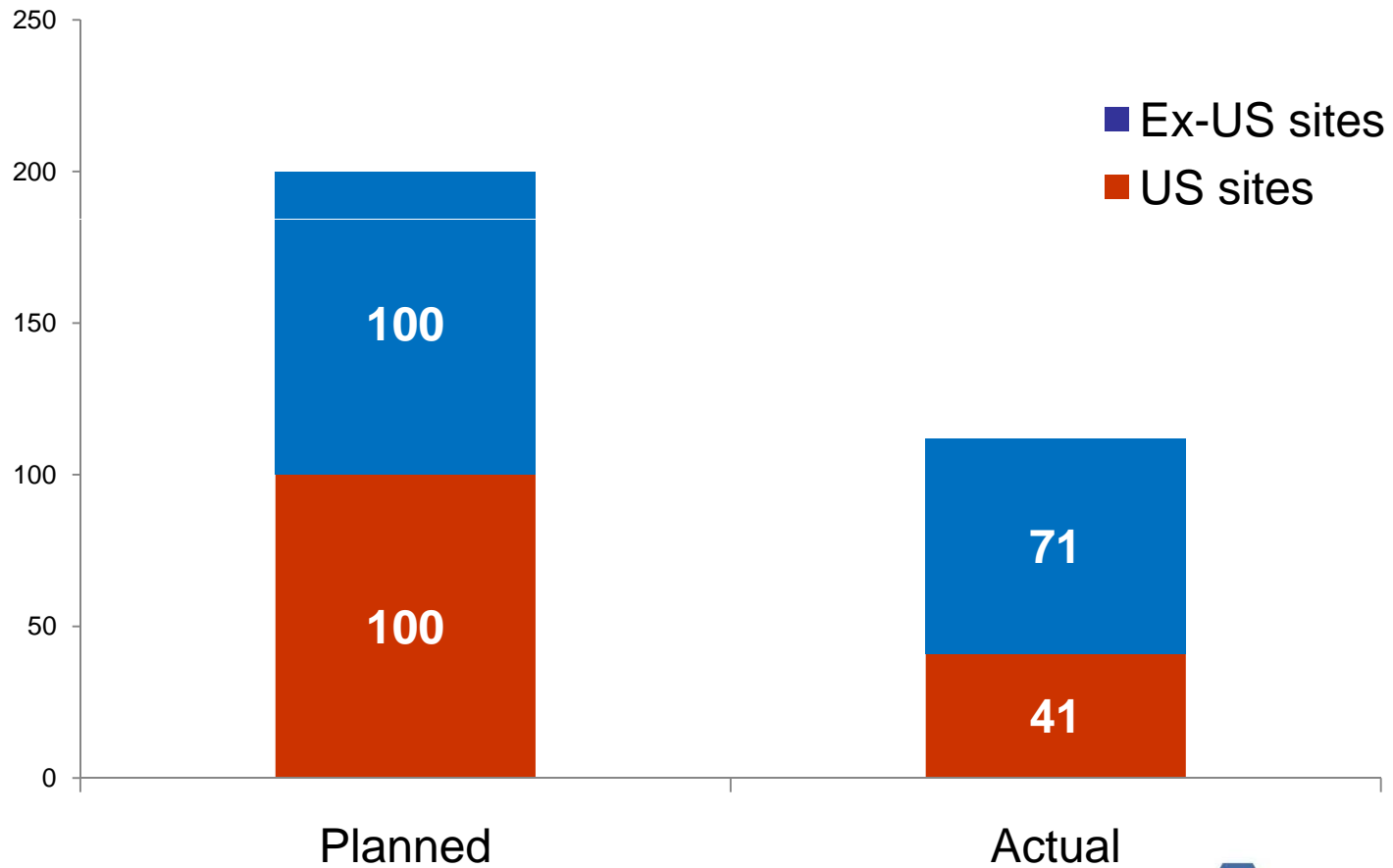
- Phase III Study
- 100 US Sites
- 100 Ex-US sites across 23 countries
- 600 subjects (780 to be screened)
- 10 month enrollment period
- Both Frozen and Ambient shipments needed
- CL Budget \$5.3mil (\$1.2mil transportation)

Transportation Costs Increased

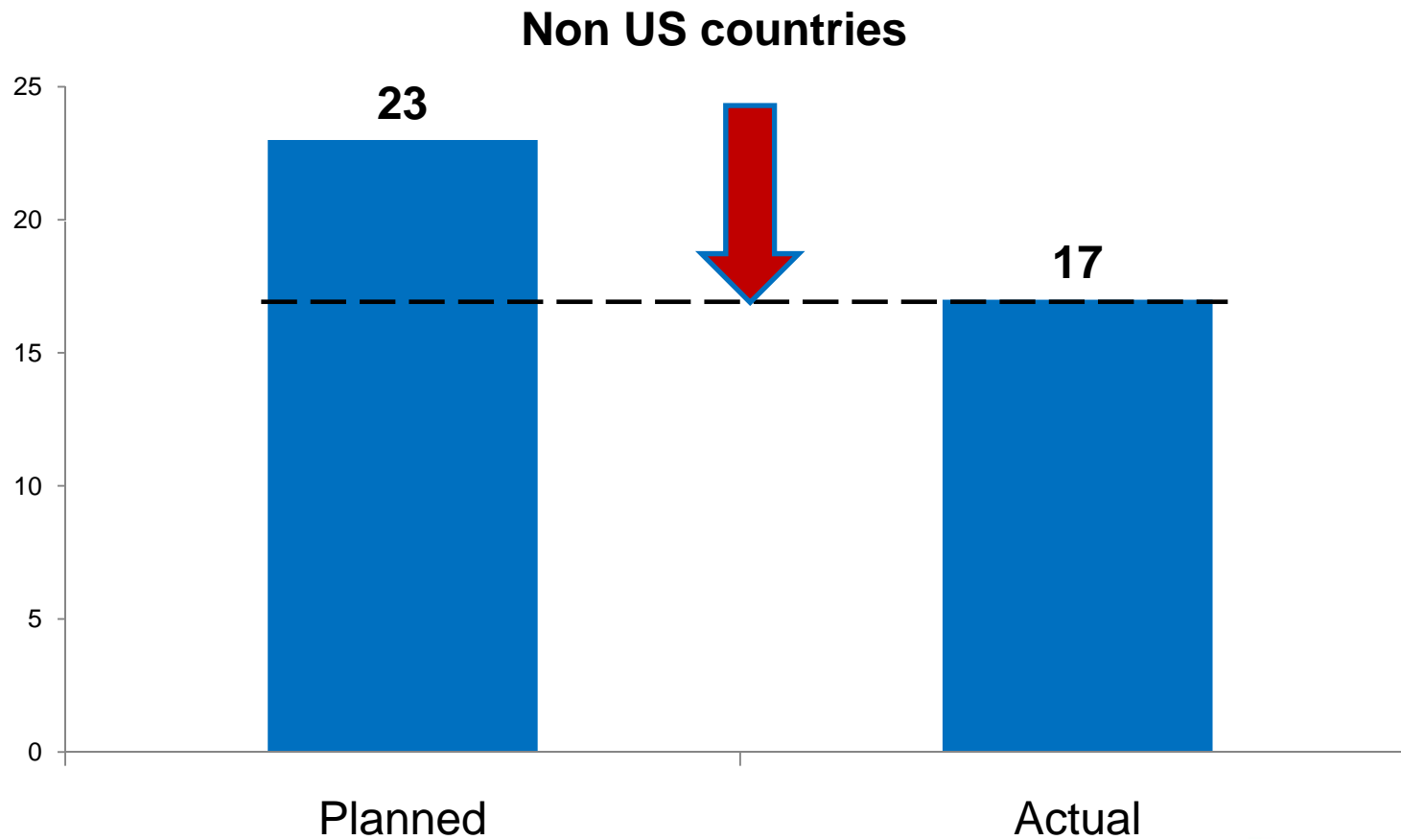
Transportation Budget (\$mil)



Number of Sites Decreased



Number of Countries Decreased

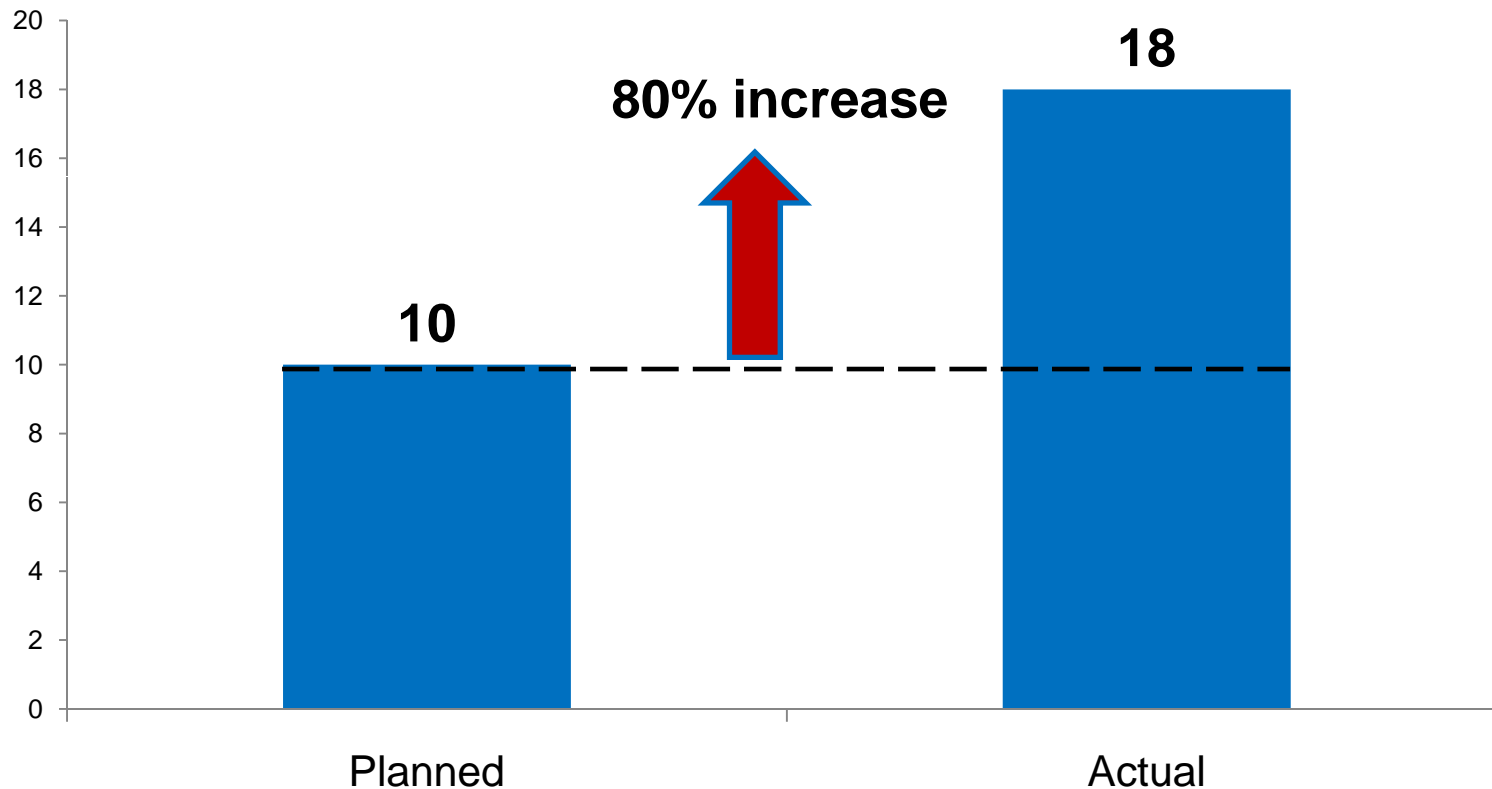


Challenges with Implementation

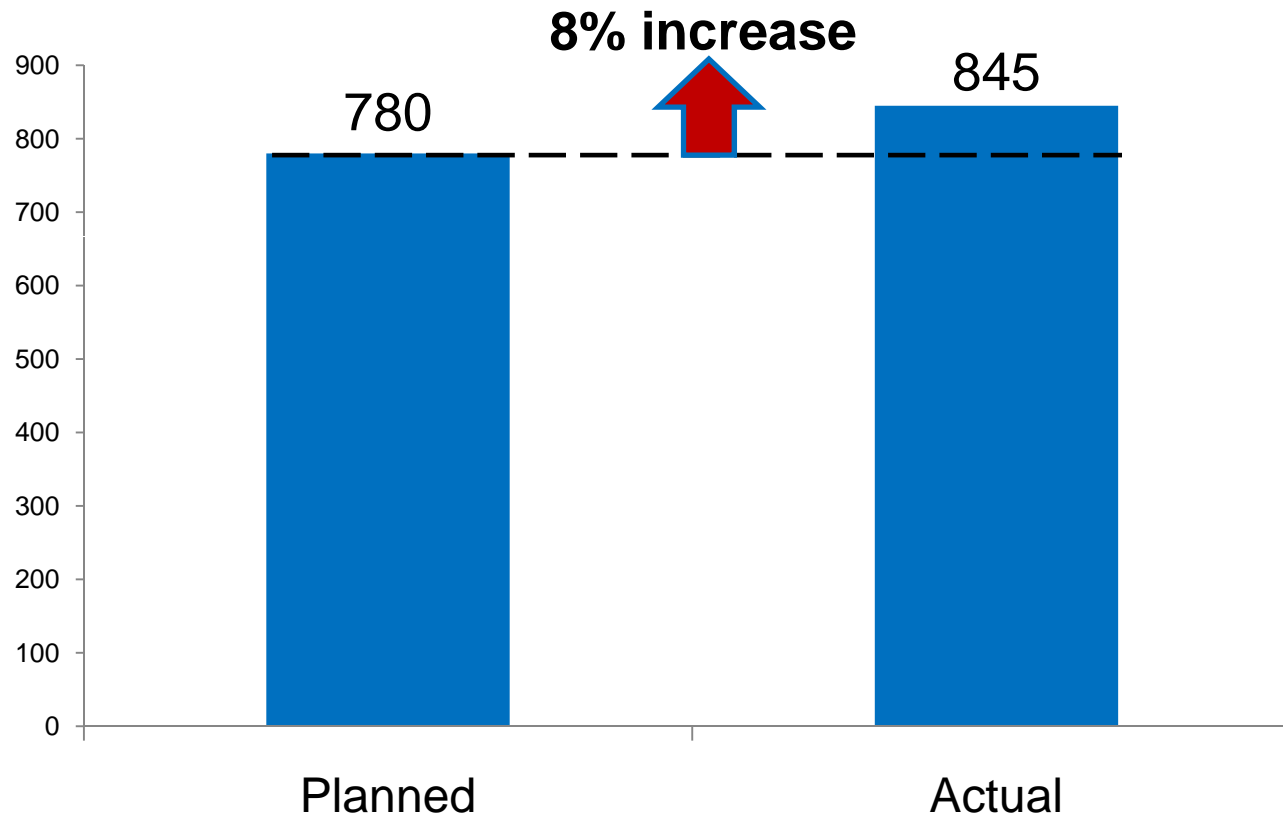
- Study sites were in more remote locations than originally proposed causing an increase in the transportation costs.
 - The further a site is from the Gateway City location used to estimate the costs, the more expensive transportation becomes.
 - For example, a gateway city estimated at \$470 turned into a remote city with actual costs of \$1125 per package.

Enrollment Period Increased

Enrollment period (months)



Screened Subjects Increased










Challenges with Implementation

- Outbound shipments increased due to lengthened enrollment time and increase in screening numbers. (as did the direct costs)
 - Kits now expired and replacement kits needed to be sent to sites
 - More kits needed to be sent to some sites due to the distribution of subjects across the sites.

Challenges with Implementation

- Subject screening was not as predicted.
 - Screening had to be extended due to a higher amount of screen failures than estimated.
 - From 10 months to 18 months
 - More subjects had to be screened to meet the enrollment goal

Challenges with Implementation

Plan	Change	Actual
100 US Sites		41 US Sites
100 Ex-US sites across		71 Ex-US sites
23 countries (50%)		17 countries (63%)
600 subjects	=	600 subjects
780 to be screened	8% increase 	845 screened
10 month enrollment period	80% increase 	18 month enrollment period
CL Budget \$5.3 mil		CL Budget \$5.0 mil
\$1.2 mil transportation		\$1.7 mil transportation

- Review the transportation budget regularly using MCC Metric 13
- Amend the Agreement once all sites have been identified
- Amend the Agreement once all subjects have been enrolled.
- Partner with your CL provider to come up with alternate transportation solutions.