

# Adopting Metrics to improve performance of your Clinical Laboratories

**Karolyn Jackson**  
**AstraZeneca**

**May 2011**



## Agenda:

- Reviewing MCC Laboratory Metrics
- Exploring ways in which metrics bring value to trial operations
- Strategies for sharing metrics between sponsors & providers
- Performance metrics: a future perspective



# REVIEWING MCC METRICS



# MCC Metrics evolution



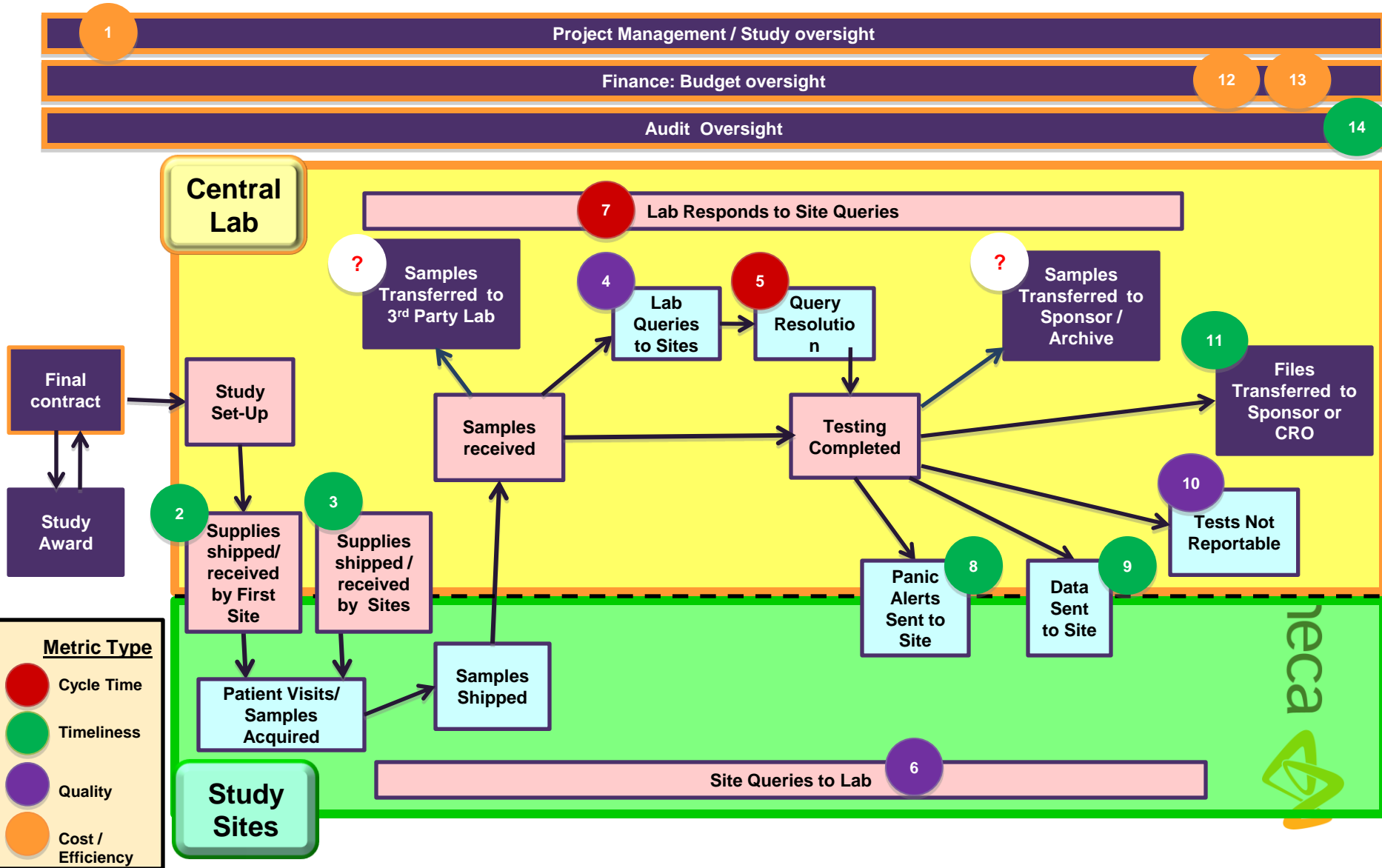
# Central Laboratory Performance Metrics v1.1

Metric	Metric Type	Metric Title	Metric	Metric Type	Metric Title
1	Cost / Efficiency	Project management turnover	8	Timeliness	Percentage of panics that had both 1 <sup>st</sup> attempt made and were successfully communicated to the sites within the defined turn around times
2	Timeliness	Percentage first supplies shipped on time to the first site for first patient	9	Timeliness	Percentage specific tests reported within expected turnaround time
3	Timeliness	Percentage first supplies shipped on time for all sites (all regions)	10	Quality	Percentage tests not reportable
4	Quality	Percentage of queries from central laboratory to site based upon requisitions received	11	Timeliness	Percentage on time accepted file transfers
5	Cycle Time	Average turnaround for resolution of queries from central laboratory to site	12	Cost / Efficiency	Plan, Forecast and Actual Financial Report
6	Quality	Percentage of queries from site to central laboratory based upon requisitions received with average turnaround time	13	Cost / Efficiency	Comparison of budgeted and actual transportation costs by region and/or country
7	Cycle Time	Average turnaround time on queries from site to central laboratory	14	Timeliness	Percentage of audit findings closed within sponsor and central laboratory agreed upon timeframe

**Version 2.0 will include a new feature - guidance regarding metric reporting expectations for each metric (i.e. Lab/Sponsor/Study /Site levels).**



# Central Laboratory Performance Metrics v1.1



# EXPLORING WAYS IN WHICH METRICS BRING VALUE TO TRIAL OPERATIONS



**Laboratory metrics are measures across the whole process:**

**Training, Investigator site performance, courier, laboratory logistics, laboratory performance**

- What can you measure?
  - Which metrics to apply?
  - Who can use the metrics?
  - Who are your customers?
  - Where does the metrics bring value?
- One size fits all or apply an adaptive model?



# Examples of Customer groups

- Procurement / Outsourcing
  - Clinical Project Leadership
  - Clinical Delivery Team
  - Site monitors
  - Site Investigators
  - Quality assurance
  - Therapy area leads
  - Supplier team ( BDE, PM, Ops, Lab Director )
  - Science Teams ( PK, genetics, biomarkers, research )
  - Biobank
- 
- Customers will have different needs and interests
- 
- Key to target the information to the customer /need
  - The degree of information granularity will change



# Metrics & Key Customer groups

- Identify key customer groups
- Consider the process
- Identify where & how you can deliver 'value'
  
- Example: Study Team & Procurement / Outsourcing
  - Plan, forecast & actual spend
  - Comparison of budgeted & actual transport costs
  
  - High level overview – total spend
  - Granular report – overall spend, segmented spend ( testing, project & data management, supplies, transport )



# Budget oversight – high level

Protocol	Start Date	End Date	Last Patient Visit Date	Total Budget	Total Spend	Budget Variance	% Invoiced	Comments
Study 1	8/15/08	09/28/09	08/01/09	\$ 35,951.00	\$ 44,019.38	\$ (8,068.38)	122%	
Study 2	10/5/09	31/03/2011	14/10/2010	\$ 77,456.56	\$ 84,419.85	\$ (6,963.29)	109%	
Study 3	12/5/06	06/30/10	16/04/2010	\$ 1,986,840.00	\$ 2,042,782.35	\$ (55,942.35)	103%	PA amendment under discussion
Study 4	4/28/06	22/06/2010	29/01/2010	\$ 3,769,728.47	\$ 3,814,050.12	\$ (44,321.65)	101%	
Study 5	7/15/09	12/07/09	11/27/09	\$ 105,626.97	\$ 105,395.80	\$ 231.17	100%	
Study 6	01/05/2007	30/10/2009	11/07/2009	\$ 73,803.51	\$ 73,556.44	\$ 247.07	100%	Budget forwarded for review
Study 7	4/7/08	05/04/10	01/08/10	\$ 269,432.33	\$ 258,987.27	\$ 10,445.06	96%	
Study 8	5/3/07	31/12/2010	30/07/2010	\$ 290,937.31	\$ 278,366.94	\$ 12,570.37	96%	
Study 9	12/1/06	12/31/10	16/10/2010	\$ 306,671.51	\$ 282,984.82	\$ 23,686.69	92%	
Study 10	11/20/06	06/30/10	08/28/09	\$ 65,401.77	\$ 59,090.45	\$ 6,311.32	90%	
Study 11	9/30/06	31/08/2010	14/10/2010	\$ 1,229,600.86	\$ 1,074,815.79	\$ 154,785.07	87%	
Study 12	3/15/04	31/01/2011	29/05/2010	\$ 117,934.15	\$ 101,743.15	\$ 16,191.00	86%	



# Study oversight – segmented initial kit supply & study kit supply

Percentage of On Time Kit Shipments								
	Q4 2009	Q1 2010	Q2 2010	Q3 2010	Target	Green	Red	Comments (if applicable)
LAB A	96.99%	88.25%	97.70%	95.29%	97%	≥97%	<97%	
Sponsor A	98.22%	83.28%	97.72%	92.98%	TBD			

The metrics provide different information to different customers

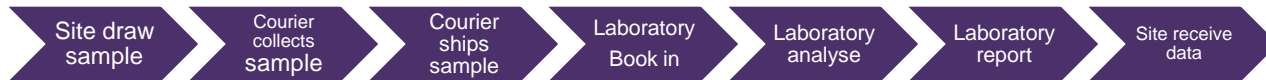
Percentage of On Time Initial Kit Shipments								
	Q4 2009	Q1 2010	Q2 2010	Q3 2010	Target	Green	Red	Comments (if applicable)
LAB A	96.86%	85.93%	97.33%	91.30%	97%	≥97%	<97%	
Sponsor A	100.00%	86.06%	97.17%	86.54%	TBD			



# Customer groups

- **Study Operations / Site Investigator / Laboratory**

## Safety Test Turn Around Time



### Metric is multifaceted

- **High level view gives view of end to end process**
- **Link to other metrics – analysis time, transport time, blood draw to courier collection**



# Safety Test Turn Around Time

> 99% of tests resulted within 48hrs  
 95%-98% of tests resulted within 48hrs  
 < 94% of tests resulted within 48hrs

METRICS: SAFETY TEST TURN AROUND TIME

SAFETY TEST BY MONTH

Month	Inside 48hrs	Outside 48hrs	% Inside	% Outside
Jan-10	2033	13	99.36%	0.64%
Feb-10	2039	19	99.08%	0.92%
Mar-10	1626	13	99.21%	0.79%
Apr-10	1005	13	98.72%	1.28%
May-10	1162	12	98.98%	1.02%
Jun-10	1331	4	99.70%	0.30%
Jul-10	1148	15	98.71%	1.29%
Aug-10	1058	4	99.62%	0.38%
Sep-10	1244	5	99.60%	0.40%
Oct-10				
Nov-10				
Dec-10				

SAFETY TEST BY TEST

Safety Test Name	Inside 48hrs	Outside 48hrs	% Inside	% Outside
CHEMISTRY PANEL	2320	14	99.40%	0.60%
COMPLETE BLOOD COUNT	2872	19	99.34%	0.66%
LIPID PANEL	2080	7	99.66%	0.34%
URINALYSIS	4065	7	99.83%	0.17%

SAFETY TEST BY PROTOCOL

Protocol	Inside 48hrs	Outside 48hrs	% Inside	% Outside
Study 1	1794	5	99.72%	0.28%
Study 2	3513	18	99.49%	0.51%
Study 3	4899	31	99.37%	0.63%
Study 4	12		100.00%	0.00%
Study 5	104	1	99.05%	0.95%
Study 6	159	3	98.15%	1.85%
Study 7	36		100.00%	0.00%
Study 8	2037	31	98.50%	1.50%
Study 9		1	0.00%	100.00%
Study 10	43	5	89.58%	10.42%

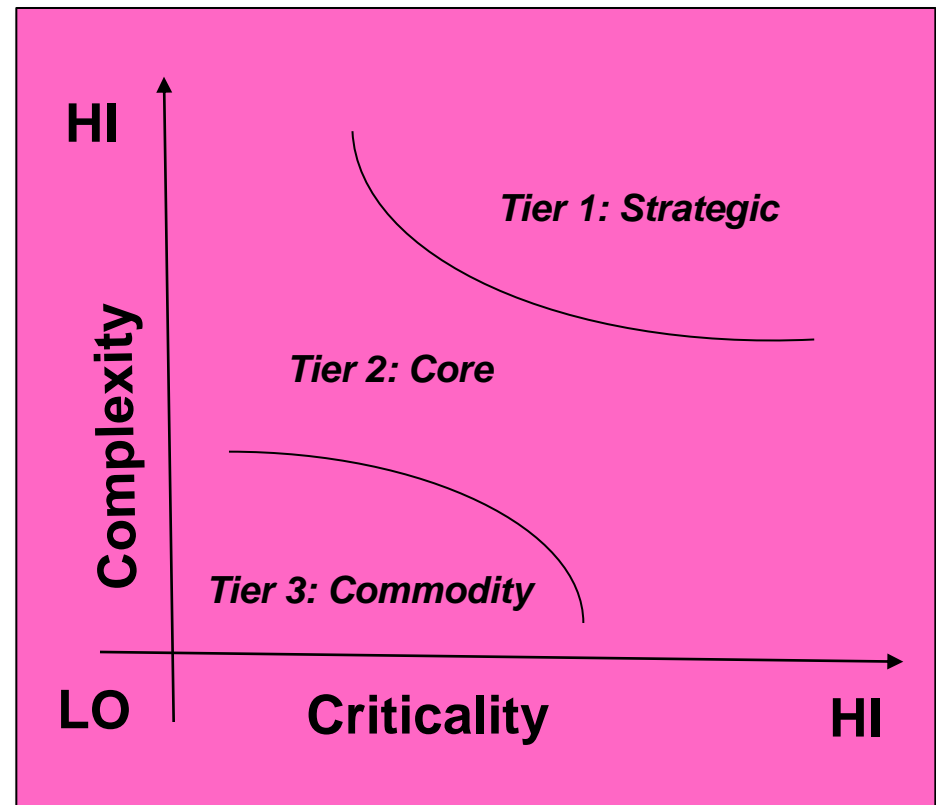


# STRATEGIES FOR SHARING METRICS BETWEEN SPONSORS & PROVIDERS



# Linking metrics to the Supplier Management framework

- Consider metrics in relation to each supplier or supplier segment
- Tailor to suit the relationship, criticality, value
- One size does not fit all



# Tailored information sharing – create the model

- Participants
  - Study Delivery, Outsourcing, Monitors, Sites, Supplier, Account Managers, Scientist
- Format
  - Metrics report (sponsor / supplier )
  - Lessons Learned ( F2F, webex )
  - Summary report
  - Dashboard
- Frequency
  - End of study
  - Key milestones
  - Fixed interval



# Success relates to 'how' we interact



# Communication & engagement



# Granularity to target improvement

**TNP BY MONTH**

Month	TNPs	Total Tests	Percentage TNP
Jan-10	444	7342	6.05%
Feb-10	457	7783	5.87%
Mar-10	132	5984	2.21%

**TNP= tests not performed**

**TNP BY LAB**

Lab Name	Total Tests	TNPs	% TNP
Facility A	31	0	0.00%
Facility B	300	2	0.67%
Facility C	16,228	392	2.42%

**TNP BY PROTOCOL (JAN-SEP 2010)**

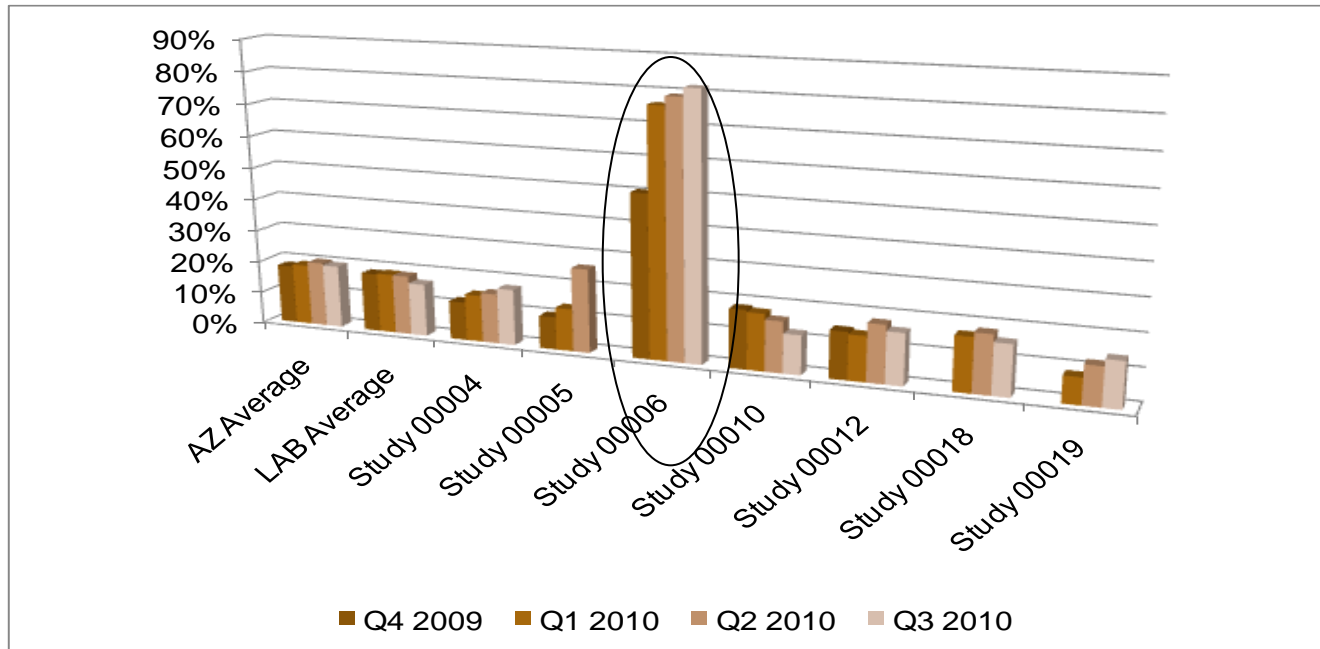
Protocol	TNP Count	Total Tests	% TNP
AZ1234	33	349	9.5%
AZ4567	713	9438	7.6%
AZ12BC	8	155	5.2%

**TNP BY INVESTIGATOR (JAN-SEP 2010)**

Investigator Name	Protocol	Total Tests	TNP Count	Percentage TNP
Dr Smith	AZ1234	3	2	66.67%
Dr Jones	AZ1234	16	10	62.50%
Dr Ano	AZ1234	222	26	11.71%



# Programme: % Samples Received with Queries

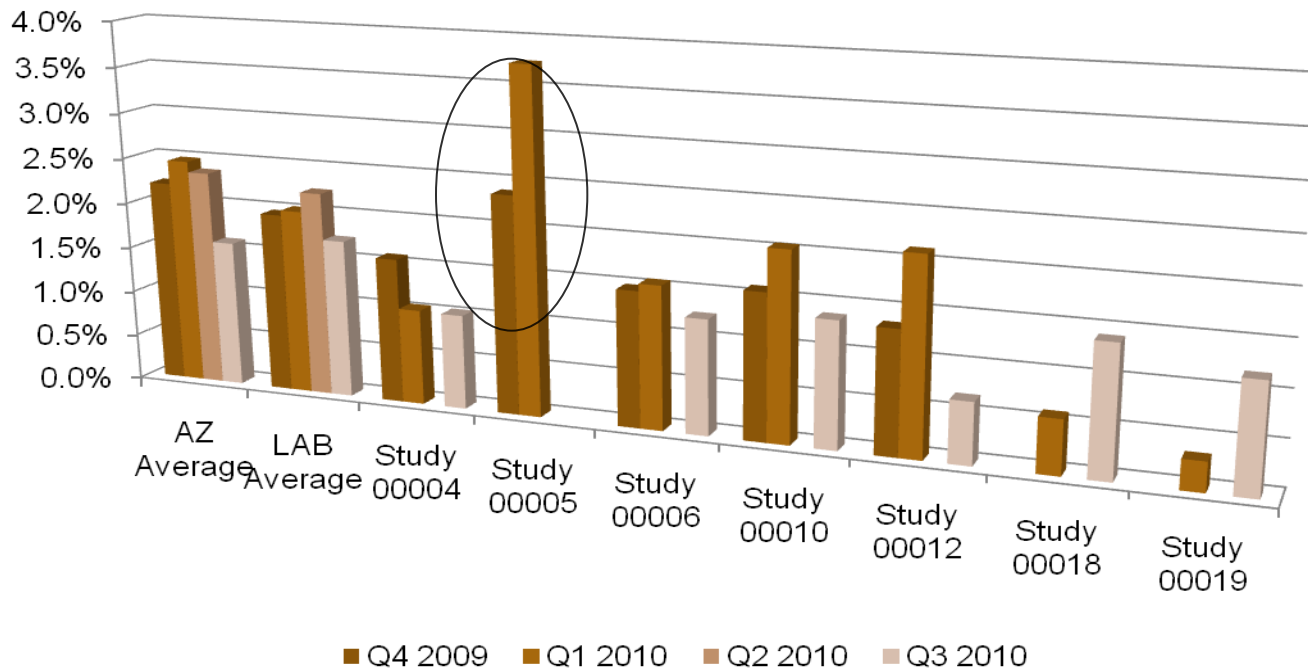


**Metrics show trend of increasing queries on one study**  
**Follow up revealed change in patient ID format from 4 to 5 digits, updated lab requisition form, sites using previous form**

**Relate to: study set-up, monitor, site**



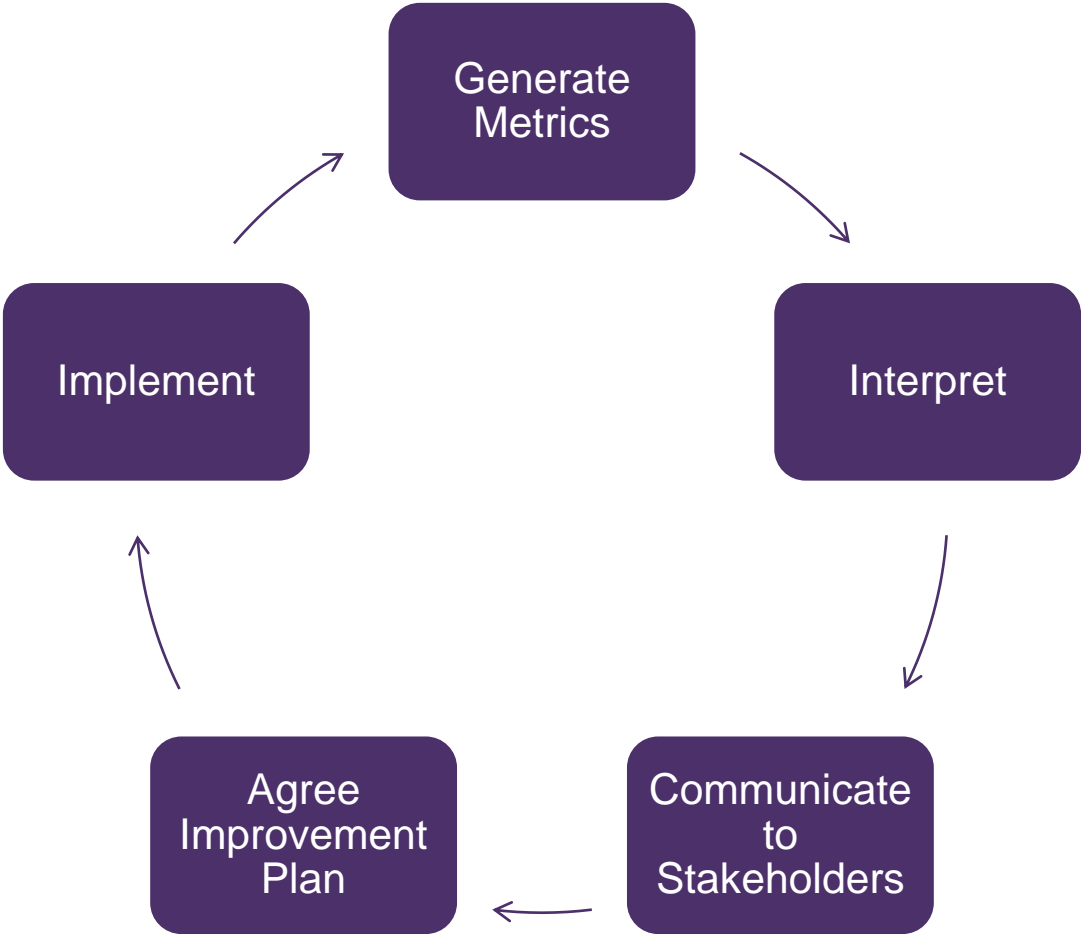
# Programme - % Cancelled Tests



**Study 5, increased % cancelled tests: samples degenerated or clotted from the Ukraine.**

**Relate to: courier, site, monitor**

# Central Lab Metrics Flow



# Conclusion

- Metrics have limited value without communication
- The following are vital for metrics to be effective:
  - Metrics must always be accompanied by interpretation – what do they actually mean?
  - Must be communicated and explained in a coherent manner
    - not all stakeholders may understand the technicalities of central lab processes
  - All stakeholders must be engaged – a regular communication platform to share metrics with all relevant stakeholders present must be agreed
  - Stakeholders must understand their role in any process improvements agreed as an output of sharing metrics
  - An understanding that sharing of metrics and process improvement are an ongoing thing and will be required for the duration of a study



# PERFORMANCE METRICS: A FUTURE PERSPECTIVE



# Where next

- Metrics are not static
- Sponsor pipelines are continually evolving
- Suppliers service models are continually evolving
- The Regulators may be expecting more
- Study complexity & geographical placements present challenge
  
- Where next .....



# MCC Learning Community

Work in progress – the Learning Community

- How to work with metrics
- How to use metrics associated with levels of complexity
- Applying metrics
  
- Funded by member usage
- Expert guidance & tuition
  
- Targeted audience content





# MCC Lab, ECG and Imaging Metrics Can Identify Quality Problems at Study Sites

<b>MCC Lab PM</b>	Query resolution turnaround time (service provider to site queries)
<b>MCC Lab PM (DRAFT)</b>	Percentage of <i>escalated</i> queries (service provider to site queries)
<b>MCC Lab PM</b>	Percentage tests not reportable
<b>MCC ECG PM</b>	Average and median time from collection of sample at the site to receipt at core lab
<b>MCC ECG PM</b>	Percentage of data queries from core lab to site
<b>MCC ECG PM</b>	Turnaround time on resolution of site queries from core lab (resolved queries)
<b>MCC ECG PM</b>	Outlier Analysis of query resolution time (resolved queries)
<b>MCC ECG PM</b>	Listing of queries outstanding >2 weeks (unresolved queries)
<b>MCC ECG PM</b>	Percentage of ECGs that have suspect quality as determined by the core lab
<b>MCC ECG PM</b>	Percentage of ECGs in which no parameters could be assessed
<b>MCC ECG PM</b>	Percentage of ECGs in which only the interval duration measurements could not be assessed
<b>MCC Imaging PM</b>	Average number of calendar days from image acquisition to image receipt
<b>MCC Imaging PM</b>	Percentage of suboptimal (but evaluable) images
<b>MCC Imaging PM</b>	Percentage of non-evaluable images versus total received
<b>MCC Imaging PM</b>	Percentage of non-evaluable baseline images
<b>MCC Imaging PM</b>	Percentages of missing imaging visits
<b>MCC Imaging PM</b>	Percentage of site queries
<b>MCC Imaging PM</b>	Average number of calendar days an imaging query is outstanding

1



# Future opportunity – meeting expectations

- Laboratory metrics extend beyond the Central Laboratory
- Metrics can open the door to improving operational standards across the broader sector of laboratories
- Many Central Laboratory metrics could be ‘core’ in a variety of laboratories
- Core metrics supported by sector specific quality metrics  
( not to confuse metrics with analytical quality control )



# Laboratory metrics evolution: new opportunities of

