

How to Improve Quality

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What is Quality



What does Quality mean to you?



What is Quality?

- Quality is:
 - ✓ Conformance to requirements (regulatory and other)
 - ✓ Satisfying the needs and expectations of the client
 - ✓ Freedom from deficiencies
- Purpose of quality
 - ✓ Customer satisfaction
 - ✓ Consistency and reliability of service

Ultimate goal is to build a trusting partnership which is a win-win for all stakeholders



- Challenges
 - Subjectivity
 - Acceptability criteria may differ across assignments and across different stages of a project
 - Not always possible to come up with a standard measure
 - The ideal quality metrics may not be possible to define
- However, essential to define metrics which can be “acceptable” and can remove some (if not all) subjectivity from measurement of quality
- Quality measures have to be derived from various tangible parameters and criteria, and also those related to perception
- Metrics should be based on a sound understanding of deliverables and stakeholder expectations



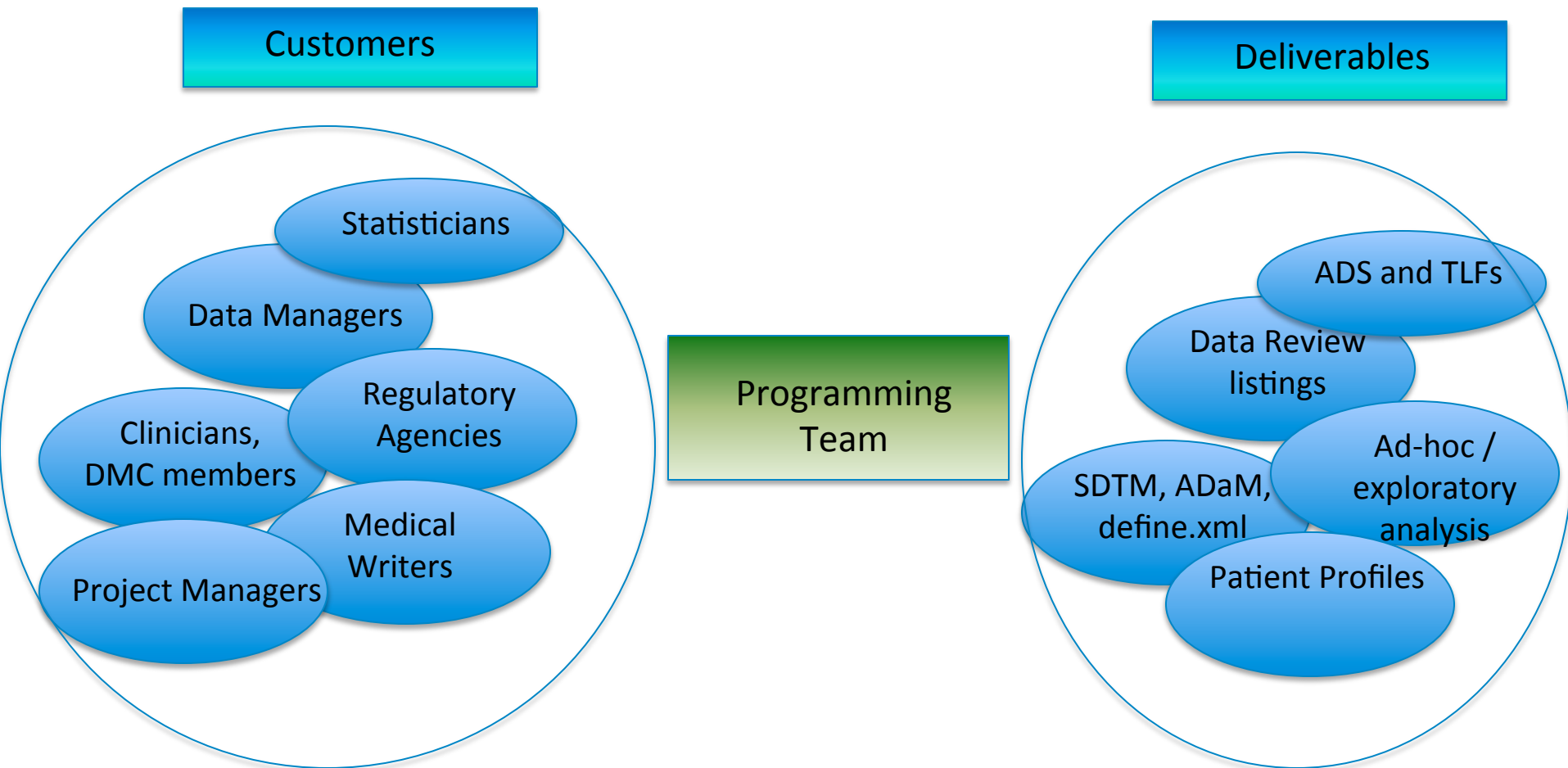
QUALITY IS NEVER AN ACCIDENT; IT IS ALWAYS
THE RESULT OF HIGH INTENTION SINCERE
EFFORT, INTELLIGENT DIRECTION AND
SKILLFUL EXECUTION, IT REPRESENTS THE WISE
CHOICE OF MANY ALTERNATIVES!

William A. Foster



Programming: Key Levers for Quality





- Customers can be internal or External and the deliverables can be for internal use or for regulatory submission.



- Managing Customer Expectations and Perception
 - ✓ Customer focused strategy
 - ✓ Clear, transparent and timely communication
 - ✓ Building relationship with customer
- Business Results
 - ✓ Reliability: Accuracy of the results
 - ✓ Efficiency: Ability to handle real life data scenarios, exception handling
 - ✓ Process Adherence
 - ✓ Maintainability: Adaptability, portability across projects



- Customer focus
 - ✓ Identifying the end customer and their role in overall project
 - ✓ Understanding customer needs
 - ✓ Criticality of the task – regulatory submission, decision making or ad-hoc
 - ✓ Project milestones
 - ✓ Tasks involved and the RACI
 - ✓ SLAs and TAT

- Communication
 - ✓ At Right level, right time by right person
 - ✓ Proactive communication
 - ✓ Transparency
 - ✓ Responsiveness

- Process Adherence
 - ✓ Adherence to applicable SOPs/WI and regulatory guidelines
 - ✓ Data security and confidentiality
 - ✓ Detailed documentation



- Leadership Role

- ✓ Involvement in project
 - Coaching, mentoring, resource allocation
 - Prioritization, focus on critical milestones
- ✓ Communication
 - Listen, be approachable and accessible
 - Share success as well as learnings
- ✓ Proactive vs reactive
- ✓ Outcome Driven, Process Focused
- ✓ Commitment to success
- ✓ Lead from front



- Approach similar to SDLC (Software Development Life Cycle)
 - Treat each program you develop as a software package

SDLC Phase	Activities
Planning & Analyze	Gather requirements and identify the inputs
Design	Identify the input datasets, subset conditions, variables, merging variables
Development	Develop the program
Testing	Validation of the data/outputs
Implementation	Final run for submission
Maintenance	Updates for future use



- **Examples of quality metrics for programming deliverables -**
 - Number of critical errors identified in final deliverable
 - Percentages of non-critical errors against the overall scope
 - Compliance with Processes
 - Robustness/re-usability of the programs
 - Client Satisfaction Score



Best Practices for Improving Quality



- Analyze requirements:
 - ✓ Scope of the work, study documents
 - ✓ Availability/completeness of the input data
 - ✓ One time deliverable (eg: final outputs after DB lock) or re-runs at different time points (eg: BDR)
 - ✓ Availability of standard/re-usable programs
 - ✓ Study documents: Study design, endpoints...the sections relevant to the outputs assigned
 - ✓ CRF: how data is collected..what information is collected at what time points
 - ✓ Raw data/ mapped data: missing values, conditional variables, categorical/continuous etc. Mapping definitions.



- ✓ Converting the request to a programming plan including specifications
- ✓ Detailed programming algorithm
- ✓ Modular Approach
- ✓ Define validation strategy – validation of key critical outputs vs other outputs

- ✓ Cross-check of specifications against the study documents, data
- ✓ Availability of Reference programs
- ✓ Availability of Standard macros
- ✓ Developing programming logic



- Assignment of right skilled team members
- All outputs for a domain with same set of programmers, chances of missing out on key details are reduced significantly.

- Program Development
 - ✓ Robust/defensive programming and not data dependant programming
 - Possibility of partial dates, overlapping dates
 - ✓ In-built validation checks
 - Use of %put statements to put appropriate messages in the log, generate supporting listings to check data, output specific scenario which may help in checking the data when new data transfer is available.
 - ✓ Clear and descriptive comments
 - ✓ Follow good programming practices
 - ✓ Evaluate specifications as programming progress and provide inputs or seek clarifications as appropriate.



➤ Perform Self Validation

- ✓ Self Review of the output before declaring the *DONE* status
- ✓ Checks against standard and study specific checklists
- ✓ Interpretation of the numbers presented and whether they make sense and are consistent with similar outputs
- ✓ Documenting the data issues, if any.



➤ Parallel programming

- ✓ Commonly followed approach
- ✓ Effective only when right skilled programmers are working “INDEPENDENTLY”
- ✓ Defeat the purpose when done with the objective of “MATCHING” both development and QC outputs



BEYOND PARALLEL PROGRAMMING.....

➤ Data checks

- ✓ Validation program should include data related checks.
(Examples: Variable range (min-max values), uncoded terms, multiple records, observations outside visit window)

➤ Consistency Review

- ✓ Cross table checks
- ✓ Consistency of numbers, formatting across outputs

➤ Statistical Review

- ✓ Outputs generated using advanced statistical procedures
(In-depth review of data/outputs involving complex derivations/analysis)
- ✓ Review of program as well as the output from the statistician



- Implementation

- Final run on the data to be used
- Quality Gate completion
 - ✓ Data and programs used are latest
 - ✓ Log check
 - ✓ All outputs included
 - ✓ All queries are resolved
 - ✓ Supporting documentation is complete

- Maintenance

- Any updates post any submission with detailed documentation of modification history



QUALITY IS A SERIOUS PART OF SUCCESS OF
ANY ORGANIZATION, AND IF IT IS NOT
INTEGRATED IN THE DAY-TO-DAY WORK LIFE,
IT WON'T HAPPEN!



- Partnership between customer-vendor is critical for high quality outputs
- When only part of work is outsourced the teams may have limited understanding of cross-functional activities, functional challenges , priorities which may led to substandard quality
- Unrealistic expectations from customer
- Over commitment from the vendor
- Proactive and transparent communication

**QUALITY IS NOT WHAT A SUPPLIER PUTS IN,
IT IS WHAT THE CUSTOMER GETS OUT AND IS WILLING TO PAY FOR.**



Examples and Case Studies



Example 1 - Frequencies

•Incidence of Laboratory Abnormality table:

Incidence of Laboratory Test Abnormalities (Without Regard to Baseline Abnormality)

				Group A		
Number of Subjects Evaluable for Laboratory Abnormalities				10		
Number (%) with Laboratory Abnormalities				10 (100%)		
GROUP	PARAMETER	UNITS	CRITERIA	N	n	(%)
HEMATOLOGY	Hemoglobin (HGB)	G/DL	<0.8x LLN	10	10	(100.0)
	Hematocrit (HCT)	%	<0.8x LLN	10	0	(0.0)
	Red Blood Cell Count	10**6/MM**3	<0.8x LLN	10	1	(10.0)
	Platelet Count	10**3/MM**3	<0.5x LLN	10	1	(10.0)

Haemoglobin results abnormal for all subject?

- Is this an Anaemia study?
- Is there some data issue?
- Is there a mapping issue?

-While mapping the result was converted in G/DL. The units for the normal ranges were G/DL but the normal range values were not converted to same unit.



Example 2 – Statistical procedure output

- Proportions of responders at Week xx.

Proportion of responders at Week 48		
Outcome	Active	Placebo
Number of evaluable subjects	396	400
Responders	305 (77.0%)	346 (86.5%)
Non Responders	42 (10.6%)	11 (2.8%)
No Data	40 (10.1%)	38 (9.5%)
Point estimates of difference in proportion [1]		-0.0237
95% CI [1]		(-0.0503, 0.0029)
[1] The difference and 95% CI using stratum-adjusted Mantel-Haenszel approach over the two assays and the screening plasma HIV-1 RNA levels ($\geq 100,000$ copies/mL or $< 100,000$ copies/mL).		

The difference in proportions is -0.095 (=0.865 -0.77)
And the point estimate using adjusted Mantel-Haenszel is -0.0237....does it make sense?

- The statistical procedure used was correct but the data used was not correct.



- Unavailability of clear specifications from customer for data (eg: vendor data), algorithms or frequent changes in the derivations/algorithm.
 - ✓ Cross functional interactions, involvement of SMEs
 - ✓ Formal documentation by the leads as well as proper comments in the programs to explain the scenario and the decision along with reference to communications sent.
 - ✓ In-depth review of the outputs
- Large scope with very stringent timelines
 - ✓ Working together with customer
 - ✓ Focus on key datasets, outputs
 - ✓ Aim for no critical errors



Case Study 1: Impact of good Project Management skills on Quality

Situation

Customer decided to assign a new programming task. Based on the details shared, the complexity was assessed and an appropriate team was identified. During the regular evaluation of project health it was identified that the quality aspects are not being met and a root cause analysis was performed. The primary reasons were:

- ✓ Customer processes were undergoing changes.
- ✓ Some of the tasks required more experienced team members.
- ✓ Communication challenges between the customer and vendor teams.

Solution

- ✓ Re-assessed the complexity of the work
- ✓ Re-assessed the competencies of the team members and re-defined the team structure, more involvement of senior resources for mentoring
- ✓ Further trainings of the existing team members, sharing of lessons learned, defining quality checklists
- ✓ More involvement of lead in regular communication as well as in reviews and handling queries

Outcome

- ✓ Over a period of 3-4 months the quality parameters were rated high by customer
- ✓ More confident team, ready to take more challenging tasks.



Case Study 2: Impact of inadequate Project Management on Quality

Situation

Multiple studies for a drug were assigned. There were some monthly deliverables for all these studies along with other deliverables related to DMC, BDR etc. Timelines for most of the deliverables were overlapping or back to back. Customer was expecting to build efficiencies and hence expecting the same team to work on all deliverables. Project management skills of customer PoC were inadequate and most of the time the communication was not timely and clear.

Impact

- ✓ As communication was not timely, the team had to often implement changes at the last minute, leaving very little time for review and hence the quality was impacted.
- ✓ Unclear communication resulted in re-work.
- ✓ Non-prioritization of activities leading to continuous stress on team

Learning

- ✓ Focus on planning, prioritization and communication
- ✓ Outcome driven approach by leadership



Summary



Key messages

Communication

- Transparent, consistent, clear and timely communication.

Strong Process

Backbone of the success

Domain Expertise

- Sound understanding of data and statistical methods
- Strong programming skills

Cross-functional Understanding

Good understanding of other functions - focus on individual categories is not enough.

People & Team Work

- Right skilled team members involved at right time and in right role
- Quality of our work depends on quality of our people



Key messages

Good Documentation Practices

- An essential part for quality maintenance and improvement

Knowledge sharing

- Leverage best practices
- Learn from the mistakes and ensure those are not repeated in future

Passion for continuous Improvement

- Driving an ongoing constructive dissatisfaction of current performance and a passion for continuous improvement.

Leadership Commitment

Leadership commitment is critical to success- complete involvement and leading front.



Questions?



THANK YOU!

