Moving beyond jargon

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Our goal

Quality in the Design, Conduct, Analysis and Reporting of all Clinical Trials

“Quality is the absence of error that matters” – Martin Landray, Oxford
The Juran Trilogy

1. **Quality Planning** – establish quality goals; identify customers and their needs; develop product features that respond to customer needs; develop processes that are able to produce those product features; establish process controls, and transfer plans to operating forces

2. **Quality Control** – evaluate actual quality performance; compare actual to quality goals; act on the difference

3. **Quality Improvement** – establish infrastructure needed to secure annual quality improvements; identify improvement projects; establish teams for each project; provide resources, motivation and training for teams to diagnose root cause, establish remedies and hold the gains.

   **A unifying concept that extends companywide**

“What matters” in a trial?

It Depends:

* On Trial
* On Patient population
* On Study Drug
* Etc.

One size doesn’t fit all.
“What matters” in a trial?

1. Enroll the right patients, who have given informed consent – and continue to give consent based upon most current information.
2. Properly randomize patients and maintain blind (as appropriate).
3. Conduct all critical study procedures correctly and on time.
4. Collect and report all material adverse events for all participants at all time points.
5. Collect and report all primary efficacy measurements for all participants at all relevant time points.
6. Ensure patients do not take important, contraindicated concomitant medications.

What is an acceptable error rate for each of these? How do you measure that error rate and how do you ensure you achieve your acceptable limit during the trial?