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Fear and Longing in Clinical Research

By Norman M. Goldfarb

The recent CHI Summit for Clinical Ops Executives (SCOPE) conference in Orlando offered over 1,800 attendees a good opportunity to assess the state of the industry *vis a vis* progress in adopting new processes and technologies.

The SCOPE exhibit hall made it clear that we have no shortage of important and exciting technological innovations. In contrast, the educational sessions made it clear that the adoption of innovation is very slow — some of the slides were pertinent a decade ago. As a case in point, six years ago, the FDA published the guidance, "Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring," and it could easily be a decade or more from today before RBM is widely adopted.

Why is the clinical research enterprise so slow to innovate?

First, let's define innovation broadly — from being the *first in the industry* to do something new to adopting a new process or technology for the *first time in an organization*.

Could it be that the status quo is acceptable? Hardly. The cost of drug development is skyrocketing, clinical study timelines are getting *longer*, subject recruiting is getting harder, there is a shortage of capable clinical research professionals, etc. We sorely need innovation to protect the viability of the clinical research enterprise.

Could it be that we do not want to innovate? Unlikely. If asked to vote, industry professionals would probably vote with near unanimity that innovation is not just desirable but essential.

So, if we agree that the status quo is not sustainable and the at least part of the solution is innovation, what is holding us back? We have the *longing*, so what is the *fear*?

The fear of *attempts* at innovation is completely understandable. Too many people have seen innovation projects disappoint, fail completely, or even make things worse. (EMR data entry anyone?) And that's after consuming way more time and money than anyone expected. Why should we believe that the next "great" innovation won't drag us down the same rat hole?

Well, it probably will unless we innovate according to the following time-tested principles:

- Choose your innovation carefully. Pick the one with the best combination of risk and reward. In some cases, you will want to go after the low-hanging fruit; in other cases, you will want — or need — transformation. Innovations that have already been proven elsewhere pose lower risks. Innovations that employ standards leverage advances across the industry.
- Starting with an open mind, create a clear vision of the endpoint to unify the effort and keep people motivated. Is that endpoint really worth it?
- Set reasonable expectations. Everyone loves can-do optimists, but not so much when their projects fail.
- "If you fail to plan to plan to fail." Those can-do optimists are eager to get on with it, but thorough planning, including risk assessment, is essential.
- Use rigorous project management principles and methods. Don't try to wing it.
- Test, learn and adapt as you go along. Two steps forward and one step back is still one step forward. Save mission creep for Phase 2.

- "If you want to go fast, go alone. If you want to go far, go together." Unless all the important stakeholders — and maybe all the stakeholders, period — support and designate capable participants in the innovation project, you might not get very far with it. You will also need someone with juice to protect the project when it hits the inevitable rough spots or competing priorities.
- And, finally, of paramount importance, find the right project leader. Unless you have people who specialize in innovation, you are probably looking for someone who already has a full-time job and must really, really want the innovation to succeed. He or she might see the project as their stepping stone to a promotion. But does the presumed project leader have the time, the expertise, the tenacity, and the leadership skills to drive the project to a successful conclusion?

Can the clinical research enterprise survive without innovation? Perhaps, but there is no law of nature that says new medical treatments have to reach the public. However, there is a law of nature that says the cost of medical treatments can't grow to the sky, which is where they seem to be heading. Another law of nature says that medical treatments can't save lives until patients can get them. We have to respect these natural laws. The harsh reality is that the clinical research enterprise must innovate to survive — it really is a matter of life and death.

Author

Norman M. Goldfarb is Editor of the Journal of Clinical Research Best Practices. Contact him at 1.650.465.0119 or ngoldfarb@magiworld.org.

