JOURNAL OF CLINICAL RESEARCH BEST PRACTICES
Vol. 12, No. 12, December 2016 "Happy Trials to You"

An Organizing Principle for Innovation in Clinical Research

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It costs too much and takes too long to develop new drugs and medical devices. In some respects, clinical research is becoming more efficient, but in others, we seem to be losing ground.

At KNect365's recent Partnerships in Clinical Trials (PCT) conference, the speakers explained numerous ways to innovate and improve the clinical research process. Nevertheless, progress is slow and halting. Perhaps what we need is an organizing principle to help drive the process of innovation.

The best-known organizing principle in physics is a formula:

$$E=MC^2$$

Energy (E) equals mass (M) times the speed of light (C) squared

Clinical research is not physics, but perhaps we can define an organizing principle to help drive the process of innovation. The following formula might do the job:

$$I=MC^2$$

Innovation (I) equals Method (M) times Collaboration (C) squared

In this formula, Innovation drives improvements in efficiency and effectiveness, Method consists of the technology and processes embodied in the innovation, and Collaboration comprises the working together of contributors to put innovation into practice. According to the formula, doubling Collaboration quadruples Innovation.

A Method has two important properties: impact and difficulty. An easy, high-impact Method is superior to a difficult, low-impact Method. However, a difficult, high-impact Method may or may not be superior to an easy, low-impact Method.

Innovation is not a linear process. A threshold level of effort must be achieved to push an innovation to completion. Fifty percent of an innovation is no better (and may be worse) than no innovation.

Contributions to a collaboration can take many forms, but they must be meaningful. Contributors who do not carry their weight in a collaboration do not, in fact, contribute; they just detract from the collaboration.

While an author, musician or artist can create an innovation working alone (but not necessarily make it available to the public), clinical research involves multiple people, so innovation in clinical research must involve multiple people. An innovation in one organization requires relatively few contributors, but to move the clinical research industry forward in a meaningful way, the innovation must be adopted broadly, which means that many people must be involved in propagating the innovation.

The elements in the formula $E=MC^2$ are physical properties that can be measured. Unfortunately, this is not the case for the elements in the formula $I=MC^2$. Nevertheless, the impact and difficulty of Methods can be compared, and "more" collaboration can be compared to "less" collaboration. Similarly, the adequacy of a collaboration to implement a Method can be roughly assessed and compared to that in other innovation efforts.

Collaboration in the clinical research industry exists on many levels, for example:

- Team members in a project within an organization or across organizations
- Research sites in a site network
- Professionals in a community of practice
- Organizations utilizing a supplier's software or other product
- Speakers and other participants sharing knowledge at an industry conference
- Competitors adopting a common standard, e.g., CDISC data standards and MAGI standard forms
- Participants in industry initiatives like TransCelerate BioPharma, the AVOCA Quality Consortium, the Metrics Champion Consortium, and the Joint Task Force on Clinical Trial Competency

Conclusion

For many industries, improving efficiency and effectiveness through innovation by 10% over 10 years would be a modest goal. But is it overly ambitious for the clinical research enterprise? To have any chance of success, we must identify achievable Methods that can contribute meaningfully and attack them with effective Collaborations.

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