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The Big Meld: The Future Integration of Clinical Research and Clinical Care

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Clinical research started out as an inherent part of clinical care: Every patient was an experiment. Today, every patient is still an experiment, but we have also built a huge clinical research enterprise that is largely distinct from clinical care.

The clinical research enterprise has been struggling to accelerate clinical studies against a rising tide of complexity, regulatory requirements, and other challenges. The result: It now takes *longer* to start up studies, capture data, and lock the database than it did 10 years ago. The current path is unsustainable.

As the cost of developing new drugs continues to increase and patents continue to expire, pharmaceutical companies increasingly rely on increasing drug prices to generate the profits that shareholders demand. The current path is unsustainable.

The U.S. clinical healthcare enterprise is struggling — and failing — to deliver high-quality, timely, convenient and affordable care to patients. The current path is unsustainable.

SCORR's new conference, "Bridging Clinical Research & Clinical Healthcare," addressed a critical question: Can integrating clinical research and clinical healthcare create a combined system that *is* sustainable?

Patients are not going to wait long to find out. Technological advances — mHealth, the Internet of Things (IOT), the cloud, machine learning, blockchain, etc.— are moving patients to the center of the healthcare equation. Millennials are migrating from visits to brick-and-mortar primary care physicians to social community consultations and one-off, mHealth-enabled telehealth chats with remote medical professionals. Their patient-physician bonds are dissolving.

Technology companies that support these trends will have a lot to say about the shape of patient-physician interactions. Will physicians put up with all the paperwork and other aggravations of the current system when they can simply consult directly with patients from the comfort of their home for instant cash? Many healthcare services — surgery comes to mind — require in-person interactions, but an OpenSurgicalTable app can't be far off. The result will be a radical restructuring of healthcare delivery. In a competing trend, brick-and-mortar healthcare providers are consolidating, but to what extent will technology cut the community health system middleman out of patient-physician interactions? What will the community healthcare system of the future look like?

The Integrated Clinical Research and Care System of the Future

If integrating clinical research and clinical care is part of the solution to the healthcare problem, a robust, integrated system of the future will have the following (over-simplified and very ambitious) attributes:

- Clinical research will merge into clinical care (not the other way around) with re-engineered processes that accommodate the needs of both.
- Clinicians will stop thinking that research is somebody else's responsibility.
- Real-world evidence will play a much larger role, in conjunction with data from randomized clinical studies.

- Healthcare professionals and patients will see participation in clinical studies as a valid care option that is offered seamlessly (when appropriate) with established treatments. (IRBs will not reject realistic consent language about patient benefits.)
- Clinical trials will migrate to the community, with various models used to engage community physicians, pharmacists, etc. At very "light weight" sites, physicians will do what only physicians have to do, with the rest outsourced to centralized service providers.
- It will be quick and easy for clinicians to find the right study for their patients and make referrals through trusted intermediaries.
- The process of starting up a study will be re-imagined, with numerous "investigators" prepped to instantaneously "stand up" when an eligible patient emerges.
- It will be *simple* for patients to obtain healthcare or enroll in a study.
- In each therapeutic area, a high percentage of clinical research participants and clinical care patient will contribute data to a single, unified, closed-loop learning healthcare system.
- Everything that can be online will be online. For example, a study coordinator will access CTMS, eSource/EDC, eRegulatory (eISF), eRandomization/eAccountability/ eSupply and other systems with a single sign-in for seamless interoperability.
- Clinical research and clinical care data standards will coalesce or map seamlessly, so data can be entered only once and used everywhere.
- Researchers and clinicians will understand that patient-centricity is driven by the patients and not negotiable.
- A study participant's clinical research data will be as available to him or her after a study as his or her clinical care data.
- Patients will own their own healthcare data, granting access or licensing it to clinical researchers, clinicians and scientists, as appropriate.
- Pharmacovigilance and safety reporting systems will be rationalized and made more accessible and convenient.
- FDA and CMS regulations, along with insurance policies, will support integration of clinical research and clinical care.
- Ethical review of industry-sponsored research will follow a continuous flow model (as opposed to the current batch model), with daily meetings at high-volume IRBs.
- Medical and nursing schools will provide basic education on clinical research.
- The numerous points of friction — from data to culture — will be eliminated or well lubricated.
- Incentives will align to support integration of clinical research and clinical care.

Conclusion

Speakers at the SCORR conference raised a lot of issues and proposed a lot of solutions. The world is changing fast. It will wait only so long for traditional models to catch up. We know what we have to do, and to some extent, how to do it. If we want to put clinical research and clinical care on a sustainable path, let's get to work.

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