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It's About Time for Patients to Own Their Own Data

Darshan Kulkarni, Vice President of Regulatory Strategy and Policy at Synchrogenix, talks with Norman Goldfarb, Editor of the Journal of Clinical Research Best Practices

Darshan, what do you think it's about time for the clinical research enterprise to start doing?

Given the new privacy laws in Europe and California, it's about time patients own their own data.

It's bizarre that study sponsors and research sites negotiate the data ownership provisions in clinical trial agreements, but patients don't even have a seat at the table, and it's data about *them*.

The whole world seems to be restructuring itself around data, and that's certainly true for patient data, especially including genetic data connected to physiological biomarkers and health conditions. How fair is it to use a patient's data to create a new product and then sell that product back to the patient at whatever price the market might bear?

Years ago, cells from Henrietta Lacks were commercialized without her permission or any share in the resulting billions of dollars in profits. "How terribly unfair," we might say now, but aren't we doing basically the same thing today with patient data? Sure, we get the patient's consent, but I've never seen an informed consent form that mentions the possibility of enormous profits. Nor do we give patients much, if any, say about who can use their data and for what purposes. Consent forms talk about "possible future research," but that hardly tells the whole story. No surprise there, given the public's low opinion of the pharmaceutical industry.

But is it practical?

Yes. A study participant's data from a clinical trial can be connected to a blockchain smart contract that controls who can use the data and how much, if anything, they would have to pay to use it. The research site and the sponsor could get a royalty-free license to use the data for that study and perhaps certain other purposes (and maybe share in any profits from use by other researchers), but other researchers or other purposes might require payment or be prohibited. A smart contract might give the patient a discount on future drugs developed with the help of that data. Given that patients currently participate in research without any expectation of financial gain, many patients would probably let researchers use their data at no charge or donate any profits to charity.

Would this system just reduce the availability of patient data?

You could argue that patients would severely limit the use of their data or would charge exorbitant prices. However, I would argue that this system would give patients incentives to share their data and to join studies that generate valuable data. In fact, with the FDA's increasing desire for real-world evidence, patient data would be increasingly available and relevant.

Would study sponsors go along with this?

A lot of Sponsors have paid lip service to the concept. A few have even taken concrete steps to give data ownership to the patient. Wide adoption will take time, although it does seem inevitable based on current trends. Smart contracts can be written to give these organizations a share in any profits. It could also be an important patient recruitment incentive. Companies like Synchrogenix, Wego Health, Hu-manity, 23andMe and Ancestry.com are already active in this space.

But the main driver might be evolving ethical standards. Even informed consent met resistance when that idea was first introduced.

Well, Darshan, I certainly want to own *my* data…what's it worth to you?

Interviewer

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.