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Unique patient identification as a necessary condition for clinical research in rare diseases

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Abstract

Clinical and research information resides in multiple data repositories, registries, bio, and image banks, EHRs, omics collections, clinical trials datasets, etc. Some of these resources contain information about the same individuals, but matching the records or tissues is extremely challenging, as each data collection may utilize its own identifiers.

Broad utilization of patient registries and platforms and applications for patient reported outcomes (PRO), and a recent indication from the FDA on its willingness to accept PRO along with other RWD (natural histories, EHR records, etc.), require innovative approaches on identification, curation, harmonization, integration, and sharing such information in a secure de identified environment.

Data distribution of de identified information with potential secondary requests for more information from the same patients that may exist elsewhere, while fulfilling the promises to patients and research volunteers to not to expose their identities when sharing their data, demanded generation of unique identifiers for each distribution/sharing request.

The SigNET™ Platform enables scientific collaboration, integration, analyses, and distribution of research data across studies and repositories. It generates Unique Clinical Research Identifiers (UCRIs) per Patient per Study per Disease, thus permitting collaboration and sharing in rare diseases, in which utilization of "standard" GUIDs may not be enough to protect identities of patients participating in multiple research projects.

To date, the SigNET Platform generated UCRIs for 10,000+ research volunteers participating in 50+ clinical trials and observational studies in 14 countries. As about ten percent of patients are enrolled in more than one study, multiple UCRIs are generated per patient. Close to 100 academic institutions throughout the world benefit from utilizing the SigNET Platform. More than 100K cryovials with biofluids and 70K+ samples of postmortem tissues stored at multiple distributed biobanks are identified with barcoded labels containing UCRIs generated by SigNET. DNA files from close to 5K patients across several DNA repositories are identified by UCRIs as well.

The Platform allows researchers to securely collaborate and share de identified information by generating a set of UCRIs per data distribution. If collaborators are interested in finding more data/DNA/tissues/etc. from the same participants elsewhere, they may query the Platform for more information, including where and under what identifiers those records, or samples are stored.Such innovative approach and technology offer standardized, reliable, and secure way to collaborate across research continuum accelerating discoveries across academia, foundations, and the industry.

Biography

Alex is the Director of the Center for Innovation and Bioinformatics at the Neurological Clinical Research Institute at Massachusetts General Hospital and a Principal Associate in Neurology at Harvard Medical School. The focus of his work and research is conception, design, development of technology, platforms and infrastructure for collaborative clinical research and optimization of clinical research operations in a given disease network. Other areas of interest are creation and management of disease-specific research networks, understanding the benefits of patient-centric research and incentives for research collaborations.

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