Cancer biorepository speeds clinical trials, drug development, analysis shows

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Researchers at Moffitt Cancer Center say identifying and selecting participants for phase II cancer clinical trials from a centralized warehouse of patient-donated biological data expedites participant accrual, reduces trial size, saves money, and may speed test drugs through the drug development pipeline.

Their study, which analyzed datasets from recent clinical trials conducted at Moffitt, was published online March 15 in *Statistical Methods in Medical Research*.

Launched at Moffitt in 2005, Total Cancer Care is a comprehensive approach to cancer that enables physicians, researchers and caregivers to identify and meet all the needs of a patient and their family during the patient's lifetime and for future generations. At the heart of this approach is the Total Cancer Care Protocol, which allows patients at Moffitt and its partner institutions to donate excess tumor tissue and biological samples for research. The samples are analyzed for biomarkers and other unique qualities and stored in a biorepository for study. Researchers can also use the information to quickly identify potential candidates for clinical trials based on a patient's biological and molecular profiles.

Total Cancer Care enables evidence-based cancer care and helps usher in an era of personalized medicine, a concept the National Institutes of Health has invested in heavily. The authors also note that the National Cancer Institute has funded efforts to develop information and

biospecimen infrastructure projects.

Efforts to discover biomarkers for disease and the identification of genetic signatures that can guide treatment selection are driving efforts to create patient biorepositiories. And the future of molecular-based, personalized medicine will uncover new innovations, adding to the body of information available for designing clinical trials, the authors said.

Unlike Moffitt, few institutions have established the infrastructure necessary for the systematic collection and maintenance of biosamples, related molecular analysis, electronic medical records and other data from their patient populations, said study co-author Benjamin M. Craig, Ph.D., associate member of Moffitt's Health Outcomes and Behavior Program.

"By taking a systems approach, biomarker and genetic profile information not only enables personalized medicine, but also promotes comparative effectiveness research," Craig said. "The contribution of a data warehouse that integrates clinical, biospecimen and molecular data for conducting clinical trials is essential for making good decisions about resource allocation."

By conducting a "value of information" study on the effectiveness of data warehousing in conducting phase II clinical trials, the authors found that patient accrual for trials was quicker when using data from the Moffitt biorepository. They also found that fewer patients needed to be enrolled in a study and that the amount of information recovered was equal to the amount of information gleaned from trials with greater numbers of participants.

"Our study provides evidence that programs, such as the Total Cancer Care® Protocol, that follow patients and collect clinical data for storage in a common warehouse can reduce the number of patients needed for a

clinical trial without compromising the results of the study," said study lead author David Fenstermacher, Ph.D., chair of the Biomedical Informatics Department at Moffitt. "Another positive impact of using the biorepository for clinical trial participation is that phase II trials that test new cancer treatments being developed by the pharmaceutical industry move more quickly and cost less."

According to the authors, the effective assessment of new molecular-targeted therapies for tumors will be an essential part of stratified clinical trials design as trials become smaller, shorter, cheaper and more individualized. They also suggested that the development of new, molecular-targeted treatments will require the use of clinical, molecular and biospecimen data generated from the point of care.

Their analysis of the effectiveness of the Total Cancer Care Protocol, through which more than 96,000 patients have consented to donate tissue samples and clinical data for biowarehousing and analysis has shown the benefit to those conducting clinical trials and the patients participating.

"The knowledge gained from our study and other studies under way at Moffitt are providing the foundation for creating the next generation of data management infrastructure to support personalized medicine," Fenstermacher said. "As these resources mature, data assessment strategies, such as 'value of information' studies, will be imperative to understand how data can be used to enhance patient care and improve treatment outcomes through evidence-based guidelines."

More information: smm.sagepub.com/content/early/ … 80213480282.abstract

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