New approach to cancer research aims to accelerate studies and reduce cost

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A new model for improving how clinical trials are developed and conducted by bringing together academic cancer experts and pharmaceutical companies is being tested by research experts at The University of Texas MD Anderson Cancer Center.

An assessment of the alternative research model was published in the May 14 online issue of *Cancer*. The model was piloted in a multi-study leukemia research program established between MD Anderson and Bristol-Myers Squibb (BMS) and revamped how studies were designed and carried out.

Current methodology often limits patient access to and eligibility for studies, slows down drug development and increases costs. Since the 1980s, drug companies have employed Contract Research Organizations (CROs) - outside groups that have limited input from academic cancer experts and that focus on the one-drug, one-cancer approach to designing clinical trials with restrictive guidelines for patient eligibility.

The model allows researchers to arrive at findings more quickly, to conduct multiple clinical trials of pharmaceutical company drugs across several cancer types, to lessen expenses and to increase the likelihood of finding medical solutions more quickly. MD Anderson has more than 50 research partnerships and alliances with pharmaceutical companies, managed through its Strategic Industry Ventures group.

Hagop Kantarjian, M.D., chair of Leukemia and co-author, Ferran Prat,

Ph.D., J.D., senior vice president for Research Administration and Industry Ventures, believe the new research model addresses these needs.

"This cancer research model is flexible and modifiable according to existing needs because it does not pretend to create a 'one-size-fits-all' approach," said Kantarjian. "These types of alliances have significant variations that accommodate the partnering drug company—its drug pipeline, research needs, financial benefits and other considerations."

MD Anderson's collaboration with BMS led to simultaneous trials using combinations of immunotherapies and other treatments for several leukemia types including chronic lymphocytic leukemia, acute myeloid leukemia, chronic myeloid leukemia, and myelodysplastic syndrome. The trials include the first "triplet" immunotherapy study for leukemia, with results for all trials being analyzed by MD Anderson's top immunotherapy researchers.

The collaboration has already led to the establishment of a new standard of care for treatment of chronic myeloid leukemia with an altered dose of the chemotherapy dasatinib, which has proved more effective and less toxic.

The BMS collaboration has resulted in unique study approaches including:

- Allowing MD Anderson leukemia researchers exploration of BMS' immune-oncology pipeline across multiple blood malignancies.
- Providing high-risk patients, typically excluded from BMS-sponsored studies due to CRO restrictions, access to trials at the discretion of leukemia experts.
- Granting a set level of funding for all trials tied to MD Anderson

research programs with BMS without the need to negotiate on a trial-by-trial basis

"The success of this initiative has resulted in program expansion in a number of directions," said Prat. "BMS extended the program to other clinical and research departments at MD Anderson, and is partnering with other academic cancer treatment institutions. Our Leukemia department and other MD Anderson programs have also established similar alliances with leading drug industry partners."

More information: Hagop M. Kantarjian et al. Cancer research in the United States: A critical review of current status and proposal for alternative models, *Cancer* (2018). DOI: 10.1002/cncr.31522

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