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Patient-centered? Bioethics of adaptive design in clinical trials

To speed up the medicine development process, many new methodological and organizational accelerators are implemented. An organizational accelerator is an innovation in performing clinical trials aiming to develop and register investigated medicines in a shorter time than traditional drug development. One of them is an adaptive trial uses flexible design, allowing researchers to change, adapt and tailor a dosage of tested substance and to organize the trial in a more flexible way. For example, in some trials, genetic testing of a patient's biological samples allows to tailor a more appropriate agent and dosage in the trial.

Some adaptive methods are described to a potential participant as promises of more participant-oriented clinical trials offering higher chances to obtain direct benefit from participation in the study. There is very little systematic data evaluating this issue. In the proposed project, my team will systematically collect, examine and assess methods of adaptive clinical trials and organizational accelerators of trial design and performance. After receiving evidence of the risk/benefit profile, we would perform ethical analyses.

Data-driven, evidence-based ethical evaluation would provide very valuable information of interest to patients, researchers and clinicians, methodologists, data monitoring committees, research ethics committees, decision makers and legislators.