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IP Policy Forum: The Future of Clinical Trials: More Transparency and Pharmacogenomics

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THE FUTURE OF CLINICAL TRIALS: MORE TRANSPARENCY AND PHARMACOGENOMICS

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The traditional approach to Pharma clinical trials is to treat the general population as a single group. This has resulted in a large number of failures and lost opportunities in bringing new cures to market. The problem with this approach is that most candidate drugs are not effective on 100% of the population. In fact, a good number of drugs that are considered safe on a majority of the population are known to have undesirable side-effects on a small proportion of the population. Hence, there is a need for designing clinical trials that would identify patient sub-population(s) who are likely to respond positively or negatively to a drug.

ClinicalTrials.gov is an open registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. There are public drug information databases such as DrugsAtFDA[7] and the Canadian DrugBank[8] including drug targets. Next-Generation Sequencing (NGS) technologies have made accurate sequencing of human genomes affordable. A good number of genome-wide association studies have been published in the recent literature associating specific genomic sequence variations with human diseases. NGS technologies offer a great opportunity to repurpose some of those drugs by enabling the identification of the molecular basis for the positive and negative effects of these drugs on patients. Such

7. *Drugs@FDA*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/drugsatfda/ (last visited Jan. 23, 2014).

8. *Open Data Drug & Drug Target Database*, DRUGBANK, http://www.drugbank.ca/ (last visited Jan. 23, 2014).

Pharmacogenomic research can enable proper stratification of patients into responders and non-responders. Clinical trials strategies that take pharmacogenomics into account would hence need to be accompanied by 'Companion Diagnostic Kits' to determine whether a patient is likely to respond well to a drug. In order for this to occur faster and become widespread, there is a desperate need for the Pharma community to share and have access to all completed and ongoing clinical trials data. Hence, there is a need for updating the policies to prevent the withholding of clinical trials data or leaving data sharing to individual discretion.

In the coming decade, a shift in clinical trials design paradigm is likely to occur with most trials incorporating a patient stratification strategy as a key component in addition to enhancing transparency.