Covance recently formed a strategic alliance with Global Specimen Solutions giving clients access to a comprehensive and integrated solution that includes GlobalCODE®, snapTRACK® and wraparound services.

CODIFIED, READILY AVAILABLE INFORMED CONSENT

Gives an Estimated $1B First-to-Market Advantage

A large pharmaceutical company was one year into pivotal trials in the development of a Hepatitis C virus (HCV) drug and had a competitor which was three months ahead in their development. Research that came to the attention of the U.S. Food and Drug Administration (FDA) revealed an increased response to HCV treatment by patients possessing a specific IL28b genotype. These patients tended to clear the virus faster on their own. The FDA provided guidance to the pharma companies seeking HCV drug approval around genomic testing in ongoing trials to ensure balanced representation of the IL28b genotype in the new treatment and standard of care treatment arms of the trial.

Understanding the Challenge

- New FDA guidance meant further DNA testing would be required to determine if the efficacy findings were related to the treatment and not to genetic factors.
- The IL28b genotyping was not part of the original test schedule and thus was not explicitly listed in the informed consent.
- Timing was crucial as the company was three months behind a competitor for anticipated filing of the first NDA in this new Mechanism of Action for HCV treatment.

A Changing Scientific Landscape

Based on the IL28b finding detailed above, the FDA safety committee requested that the two competing companies demonstrate that their trial successes were the result of their respective treatments and not just a concentration of favorable IL28b genotypes in their new treatment arm populations. This further testing was required in order to evaluate applications for Marketing Authorization.

Critical Access to Consent Propels Success

The company had designed their trial with the ability to rapidly pivot, collecting broadly consented DNA with high collection rates, implemented electronically tracked management of specimens and their associated informed consent records, and the trial sponsor had “codified” informed consents for their specimens in a readily-available and searchable format. The codified consent associated with the specimens enabled the team to quickly confirm that permission had been given to test all patients in the study with assays such as the new IL28b genotyping assay. The testing was performed quickly, and the company was able to submit the new drug application in a timely manner, having dispelled the possibility that the observed efficacy was due to patient genotypes rather than the drug candidate.

The competitor's trial, though three months ahead in submitting their application, did not have easily searchable records of patient consent for new testing and was forced to submit a global amendment allowing new consent and collection of DNA for testing IL28b genotypes. This process was estimated to take approximately six months based on the number of investigator sites and patients involved and cost ~$1M USD for the filing alone. The efficiency gained from having the consent information on-hand and searchable allowed the sponsor to not only catch up, but bypass the competition and achieve approval first.

Building the Foundation for Timely Actionable Insights

The robust informatics and proactive management of consent gave the sponsor the coveted first-to-market designation for this new class of treatment and equated to a conservatively estimated $1B of additional revenue.

The success of this approach proves both the market need for, and power of accessibility to integrated specimen data including codified informed consent. This market gap was the foundation of building GSS and the development of GlobalCODE®, a proprietary informatics solution that gives clients access to live specimen data linked to codified informed consent and material transfer agreements so that qualified samples can be identified and used within the current study or across multiple studies. GSS has a fully proprietary, globally tested codification process that encompasses IRB/EC alternations to consent that impact specimen usage, going beyond other codification processes available in the market (REF Genomic Alliance Codification).

Building on the integrated data capability set, GlobalCODE® also provides full life cycle specimen tracking and advanced analytics capabilities using diverse data sources, such as central lab and referral lab data, information from CROs, and internal sponsor databases.

Learn more about our
drug development solutions at
www.covance.com

Covance Inc., headquartered in Princeton, NJ, USA is the drug development business of Laboratory Corporation of America Holdings (LabCorp). COVANCE is a registered trademark and the marketing name for Covance Inc. and its subsidiaries around the world.

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