WHITE PAPER

TECHNOLOGY-DRIVEN CRO:

OPTIMIZING ONCOLOGY CLINICAL DEVELOPMENT PROGRAMS VIA REMOTE MONITORING

ATLANTIC RESEARCH GROUP

Within the oncology drug development pipeline, which has increased by over 60% in the past decade, it is apparent that the oncology community is moving away from cytotoxic chemotherapy (the one-size-fits-all approach) toward more personalized and targeted therapies (1). We see the use of biomarkers increasing for dual purposes – to identify the patient population most likely to respond to a particular treatment, and to understand in more depth the mechanism of action and pharmacodynamics of a particular therapeutic. With the relatively recent demonstrations of the ability to stimulate the immune system to recognize and eradicate some cancers, there has been a tremendous rise in immunotherapy-based treatments.

Now that these highly-specialized approaches are driving the oncology drug pipeline, it is critical that your CRO understands the need for specialized approaches to drug development and offers services that will optimize the likelihood of a successful development program. ARG addresses the most dynamic requirement from an oncology-focused CRO in order to facilitate development of your new anti-cancer agent: **development, adaptation and use of technology.** In a technology-driven world, ARG is a technology-driven oncology-focused CRO.

One of the most important aspects of any oncology drug development program is timely acquisition of robust clinical trial data – data that has been monitored and verified. Unfortunately, one of the most time-consuming and expensive aspects for any drug development program is timely acquisition of robust clinical trial data, which occurs through the process of monitoring or Source Data Verification (SDV). Monitoring of a cancer trial is critical: it upholds Good Clinical Practice (GCP) requirements to ensure the integrity of data as well as the safety and rights of subjects participating in trials. Yet up to 25% of the cost of a clinical trial is ascribed to monitoring or SDV activities.

ARG understands this and has focused on using technology to reduce the time and expense associated with SDV. We incorporate **remote monitoring of clinical trial data** in the Electronic Data Capture (EDC) system to perform SDV. Working with participating institutions, including large cancer centers, our CRAs can directly access (under carefully controlled and auditable conditions) patient clinical trial data through the electronic medical record (EMR) at the clinical trial site without the need to physically travel to the site. To facilitate remote monitoring of data that is not directly incorporated into the patient's EMR, we have added fields to the EDC to allow sites to upload a scan, PDF file or even a photograph of data reports. We recognize that telemedicine is becoming increasingly important in the healthcare industry and have updated trial-specific EDC systems to allow a site to upload a recorded telemedicine session when relevant to a particular oncology clinical trial.

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In terms of how remote monitoring of clinical data facilitates clinical development in a real-world scenario, consider the current challenging clinical research climate associated with the COVID-19 pandemic. In ordinary circumstances, there are several monitoring options: one is remote monitoring via access to the EMR, but some sites do not have an EMR. Another is travel to the sites for SDV, which would be required for sites without EMR. But in the face of the global pandemic, travel to sites is difficult and in-person on-site monitoring at the clinical setting may pose health risks for patients, the site staff and the CRA. Thus, the clinical research community reasonably expects that on-site monitoring will be difficult to reliably accomplish over the coming months. This could lead to disruptions in monitoring and delays in timelines for completion of oncology clinical trials.

The ARG solution is to contact the sites to discuss methods for providing source documentation in a simple and secure manner. Sites could be encouraged to sign up for Veeva's SiteVault, a free product that can be used with their clinical trials--and one that ARG currently utilizes. This tool (21 CFR part 11 and HIPAA compliant) allows sites to not only manage their regulatory documents, but also gives them a place to upload source documentation that can be shared with CRAs who are already part of the Veeva ecosystem. As an added protection, these source documents cannot be downloaded to any local computer or whatever external data storage tool the CRA is actively using for monitoring. The result is the continuation of normal clinical trial activities. Sites now have a facile and cost-effective way to implement their own clinical trial document management system that improves collaboration capabilities with CROs and Sponsors.

At ARG, we invite you to discuss how we can use our technology focus to enhance your oncology drug development process, including development and implementation of a remote data monitoring plan that is optimized on a site-by-site and study-by-study basis.

References:

1. Informa R&D Annual Review 2019

About Atlantic Research Group, Inc.
ARG is an oncology, immunology, rare and neurodegenerative disease-focused contract research organization that provides comprehensive clinical program development services ranging from pre-launch consulting to commercialization. Founded in 2004 with the vision that every project should be highly individualized and visible, ARG has experienced consistent growth across the globe, expanding our reach to include drug and device strategic consulting, clinical trial management services, and clinical data and analytic solutions. ARG is a disrupter, using first-in-class technology platforms along with relationship-driven flexibility to optimize clinical studies because we believe everyone deserves to be well.