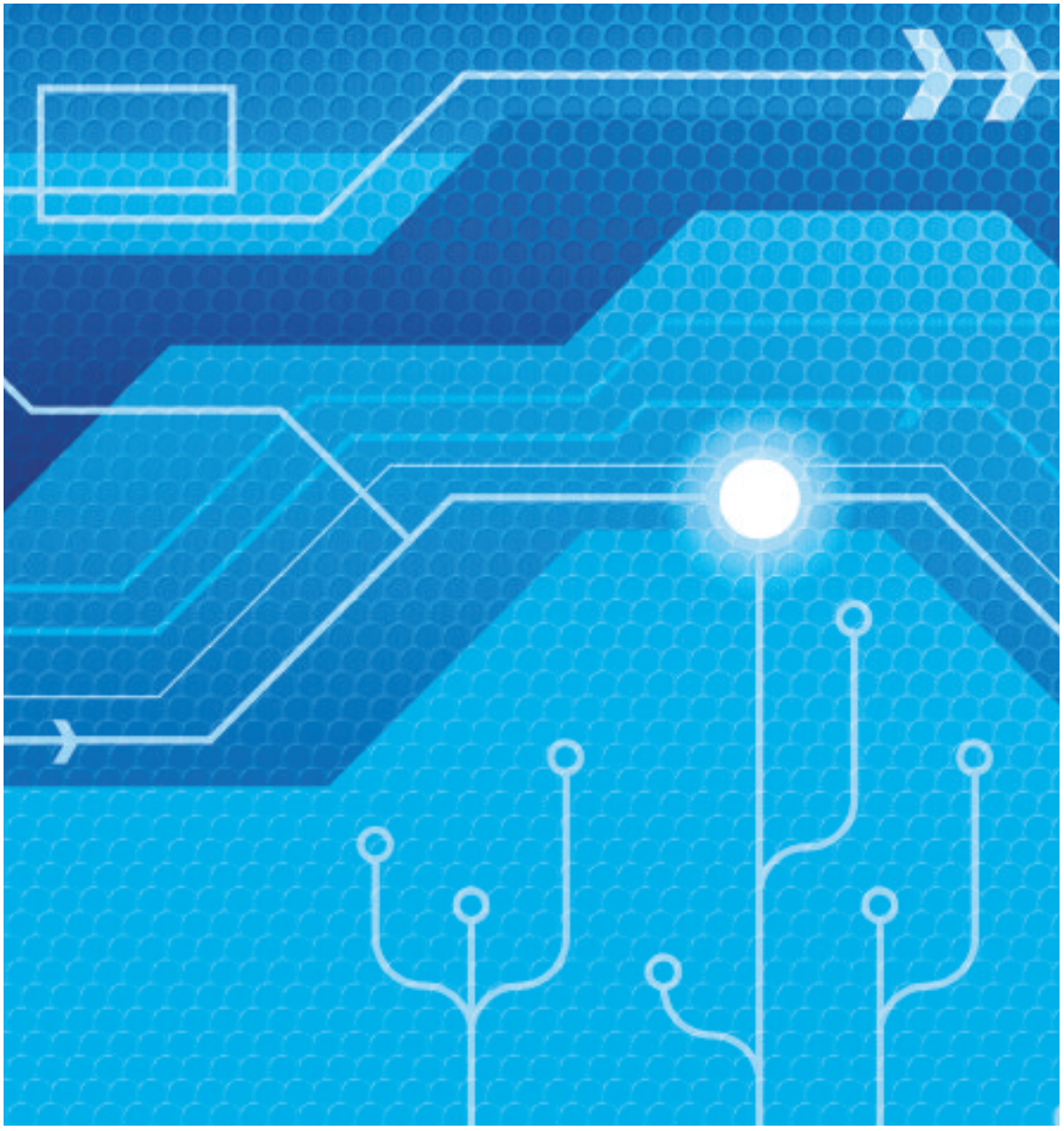

The **Big** Picture

Investigator sites around the world are the most important partners a sponsor or lab can have in their quest to determine the efficacy of new therapies, and it is vital they have the best advancements to prevent errors, particularly when it comes to image-related trials

Abraham Gutman
at AG Mednet

A common characteristic across sites is that the investigators and coordinators who participate in clinical trials are extremely busy. As a result, sponsors and labs are fearful of burdening sites with anything that might change the way in which they have always built and submitted imaging timepoints for central review. There is a great fear that key opinion leaders might revolt and choose not to participate, denying the trial from the subjects that it needs to obtain a final result. So, has the industry chosen to maintain

“According to industry research, more than half of all image-related clinical trial query stoppages result from preventable human errors, causing an average delay of up to seven weeks. Not only are sponsors losing time and money, but they also risk losing patients”

the *status quo* and settled for the inertia of the devil we know, over the possible momentum of progress? We must not forget that it was a similar approach that led to electronic data capture (EDC) taking 10 years to reach full adoption.

While resistance to change is a normal human reaction, change can produce great benefits and it does not have to be radical in order to be positive. Conversely, significant change, with the right rationale, does not have to be negative.

Take, for instance, the assembly and submission of imaging timepoints for a clinical trial. For years, sites have been asked to assemble submissions as best they can: figuring out a way to ensure that images are de-identified; completing the transmittal form, making sure the information is accurate and congruent with the images and meta-data; and checking that patient identifying information ‘burned into the image’ is redacted. After that, they schedule a courier pick up and wait for the lab to respond with any issues about the submission such as: incomprehensible handwriting on the form; the dates on the form and on the images not matching up; data not properly de-identified; or the anatomy not being complete. These kinds of preventable human errors can stall clinical trials and impact ongoing patient participation. However, with open minds and a willingness to embrace new technology, these errors can be dramatically reduced.

Feeling the Query Pain

The burden begins when sites start assembling submissions, but does not end when they are sent. In fact, one of the biggest difficulties for sites arises when data queries need to be opened, followed-up and closed. In standard trials, this problem was significantly reduced with the advent of EDC systems and the real-time data validation they provide. But what about imaging trials?

According to industry research, more than half of all image-related clinical trial query stoppages result from preventable human errors, causing an average delay of up to seven weeks. Not only are sponsors losing time and money, but they also risk losing patients. The so-called ‘big advancement’ a few years ago was using the internet to make the delivery of images faster. After all, we communicate electronically, so why not send image data electronically?

Generating and submitting trial data from investigator sites to core laboratories is not unlike an intricate manufacturing process. A complex part (in this case, a properly executed imaging timepoint meeting all protocol requirements) needed for the assembly of a final product (the results of an expert analysis of images and ancillary imaging data), must be made and delivered using the best available conveyors, assembly tools and effective processes. More importantly,

each assembled part must go through a quality control process before it is sent down the line, where it will be used as an element in a bigger assemblage. Simply accelerating the conveyor to ensure that the parts arrive faster does not make them better. With faster electronic methods to convey the data, the sites' burden of needless queries is not abated. Nonetheless, with a focus on speed rather than quality, some core labs and sponsors provide sites with primitive ways to send these images electronically.

Industry Misconceptions

There is a common misunderstanding in the industry that it is fine to provide sites with a metaphorical big dumpster and an electronic chute, and that labs will deal with data when it arrives, but sites should not be burdened with anything more. But what about proper de-identification, validated transmittal form data, properly acquired images and regulatory compliance? With significantly better ways to help sites to not only speed up the delivery of image data, but also reduce the queries and the overall time they have to spend away from their patients, we cannot continue with the *status quo* and not provide them with these new tools because we are afraid they will bolt from the project.

As an industry, we should take a more positive approach. Investigators and trial coordinators are the unsung heroes of clinical trials. They live where the proverbial rubber meets the road and should be treated as proper partners. It is the industry's responsibility to make available the best advancements in technology and present the right tools for them to properly complete the job, while reducing the time that sites have to spend on these tasks before and after submissions. Using facts, data and proper training, they will evolve just as they have in so many other areas.

Submission Quality

There are good reasons why clinical trials must accept that certain elements are not within anyone's control. We deal with human lives and, as such, a degree of randomness is always present in the process. Since patients in many clinical trials may be very ill, we must treat every opportunity to collect data extremely carefully. For this reason, every place where we can increase the quality of the submission process for the data gathered from patients is not only paramount, but an ethical imperative. Just as in the manufacturing and shipping of key subcomponents of an assemblage, problems identified and addressed at the source greatly increase the likelihood that the final product will be completed according to the original specifications.

Providing sites with the right tools to assemble and submit their clinical trial data, ensuring that the quality and completeness of their work is automatically checked prior to submission, greatly enhances the efficiency of the downstream process of converting this input into usable trial data by the core labs. By advocating the use of proper tools and a validated delivery platform for the submission of imaging data by the sites, a trial sponsor can mitigate the risks inherent in every phase of a drug development programme. Fewer errors in submission ensure the highest level of quality for their data. This, in turn, leads to more dependable analysis and better decision-making.

About the author

Abraham Gutman leads AG Mednet in its mission to improve, automate and expedite outcomes in clinical trials by ensuring quality and compliance within critical medical imaging processes. Since founding AG Mednet in 2005, more than 16,000 registered users across thousands of investigator sites in 60 countries use AG Mednet to participate in projects sponsored by each of the world's top 20 pharma, biotech and device companies. Abraham holds a BA in Computer Science from Cornell University and an MSc in Computer Science from Yale University.

Email: agutman@agmednet.com