



Clinical Researcher

The Authority in Ethical, Responsible Clinical Research

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**Navigating the Data Stream: Practical and Digital Tactics for Researchers
in Search of Direction**

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Clinical Researcher

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CHAIR'S MESSAGE

Setting the Stage for Critical Roles and Responsibilities

David J. Morin, MD, FACP, CPI, FACRP, 2022 Chair of the Association Board of Trustees for ACRP



The past three years have seen a significant evolution in research with the exploration and adoption of new ways to conduct clinical trials. Once we obtain updated regulatory guidance, our profession will collaborate on developing optimal processes for these novel methods. Central to our success will be the ongoing development and retention of a competent workforce.

As a principal investigator (PI) and practicing physician for more than 30 years, I've seen tremendous innovation in developing new therapeutics and devices that have saved or improved the lives of countless thousands. The path of seeking approval for a New Drug Application, Biologics License Application, or Investigational Device Exemption through the U.S. Food and Drug Administration is incredibly complicated and expensive, and comes with no guarantees. Central to these efforts are human beings who volunteer to participate in the necessary research and place their trust in us. It's a responsibility that requires a knowledgeable, experienced, and competent study team with proper supervision and guidance.

As a member of the [Association Board of Trustees](#) for ACRP for the past seven years, I've seen the commitment made by this organization to be a leader in the development of a diverse and competent workforce. Many noteworthy efforts have been made, and will continue to be made, to provide resources for professional growth at the [individual](#) and [institutional](#) levels by your Association.

For example, with clinical research roles yet to be recognized by the Bureau of Labor Statistics, [ACRP certification](#) is a great way to demonstrate knowledge and competence. As a PI, I'm more comfortable knowing that members of my study team are certified by an Association with the highest standards. While certification represents a milestone in one's career, it only happens with a personal commitment to prepare through study and experience. It also sets the stage for maintaining that recognition through educational resources offered by ACRP.

As 2022 comes to a close and my tenure as Chair ends, it's exciting to look back at how ACRP continues to adapt and meet or exceed the needs and expectations of clinical research professionals around the world. ACRP is your voice, which begins by actively listening to your shared concerns and suggestions. Stay involved and consider [volunteering](#) at the Chapter level or for a committee.

It's been an honor to serve and work alongside our talented Executive Director, the ACRP staff, my fellow Board members, and those who volunteer their time and expertise on our numerous committees—all of whom are there to support your efforts in your essential role as part of the study team. Our collective health depends on it!



In addition to his volunteer duties with ACRP, Morin provides patient care and serves as the Director of Research at Holston Medical Group, a multispecialty practice in Tennessee and Virginia, and is Director of the High-Risk Disease Prevention program for a Fortune 100 company.

PEER REVIEWED

Who Are the Active U.S. Principal Investigators?

Harold E. Glass, MSc, PhD; Andy Guy, MBA



Estimates about the size and composition of the U.S. principal investigator (PI) pool vary widely and are often based upon rather opaque sources. The federal [Physician Payments Sunshine Act](#) mandates the public reporting requirements for all pharmaceutical and medical device companies regarding their payments to U.S. physicians and other medical professionals. This includes separately indicated payments for industry-sponsored clinical research. The database used to capture and report these data, [Open Payments](#), requires extensive user coding and cleaning.

Drawing on user-coded and -cleaned data reported for the years 2018 to 2020, the Open Payments database indicates that the largest 20 pharmaceutical companies (by payments) account for nearly three-quarters of all payment value. The actual number of U.S. PIs has remained strikingly constant across the industry since 2014. Most investigators during this three-year period have little clinical trial experience. However, a small number of investigators account for a very large portion of all the clinical trial activity. When coded and cleaned, the database provides a near census of all active U.S. PIs and an inventory of the studies on which they worked.

Background

The overall demand for U.S. clinical investigators, according to both [ClinicalTrials.gov](#) and Open Payments, has remained remarkably constant over the years since 2013. ClinicalTrials.gov provides valuable data about the design and execution of clinical trials conducted under U.S. Food and Drug Administration (FDA) auspices. Studies include those sponsored by the

pharmaceutical industry as well as any other organizations sponsoring relevant clinical trials. The breadth and validity of ClinicalTrials.gov data have most certainly improved over time, and the database's value is now widely accepted by pharmaceutical industry professionals as well as others who use these data for study conduct and other research purposes. However, the value of Open Payments remains to a large extent overlooked. It is an operationally challenging dataset. Yet, even with these operational issues, the data provide a much more definitive overview of the U.S. clinical investigator terrain than is available through any other source.

To date, original research drawing upon Open Payments data has been limited.^{1} Similarly, the dataset is not widely used by drug development professionals. There are probably two overriding reasons for this difference in the usage of these databases. ClinicalTrials.gov has existed for a much longer period, with the number of mandatory variables increasing each year. However, just as importantly, Open Payments is much more difficult to access, often requiring a substantial amount of database development resources and activity. The basic reporting unit in this database is the individual physician payment. It is up to the user though to match payments by investigator, sponsor company, and study. Once this is done though, Open Payments can be used to assess investigator experience and even estimate comparative enrollment performance. The results reported in this paper are simple tabulations that can be replicated by anyone accessing Open Payments and completing the necessary data linking.

Methods, Data Source, and Data Limitations

The Open Payments database, as mandated by the Sunshine Act, was created to improve transparency in the financial relationships between pharmaceutical and medical device companies, on the one hand, and, on the other hand, between physicians and a range of healthcare providers receiving payments from these companies (see 42 CFR 403.902 in the *Code of Federal Regulations*). Data collection began in the third quarter of 2013 and has continued uninterrupted since. Pharmaceutical and medical device companies with at least one marketed product eligible for reimbursement from several federal patient support programs are covered by the law.

The data are released on a yearly basis (each June for the previous calendar year) and each recipient of a recorded payment can disagree with the reported information. Any dispute must be settled before the disputed data are made public. A second partial data release takes place six months after the initial annual release, that is, in January of the following year.

There are two major types of Open Payments data: general transfers of value and research payments. All payments above certain minimal requirements to all U.S. medical professionals must be reported. All companies covered by the act must provide all research payments for compounds still in development as well as any research payments in support of marketed drugs. Companies that have reached the one product threshold are not required to provide research payment data leading up to the FDA approval of their drug. However, they must prospectively begin to do so within 180 days of product approval. Open Payments Final Rule §403.910 allows pharmaceutical companies to request a delay of publication of research payment data for up to, but no longer than, four years. The data must be submitted, but publication may be withheld. It appears from the data and public statements that few pharmaceutical companies in the top 100 withhold publication of their data on any kind of a regular basis.

A comparison with ClinicalTrials.gov data demonstrates where missing data in Open Payments are concentrated. We chose a six-year comparison period to ensure that study start timings between the two datasets were as similar as possible. Open Payments reports the investigators' names (along with unique identification numbers) and addresses of 352,116 active study sites for the years 2015 to 2020. ClinicalTrials.gov, for the comparable period, reports a figure of 362,947 active U.S. study sites, usually with no investigator name and only a site's city. ClinicalTrials.gov reported 3% more sites; the publication requirements are slightly different between the databases. A direct review of the ClinicalTrials.gov data indicates that a very large percentage of these missing studies are early-phase studies from smaller pharmaceutical companies without a marketed product. To illustrate, over this six-year period there were 2,221 pharmaceutical companies reporting a total of five or less sites. More than half of these companies had only one or two reported sites.

There could be a subset of investigators who have only ever worked on predominantly early-phase studies for companies not required to report payments. However, even if such a subset

were to exist, many, if not virtually all, of these investigators probably appear elsewhere in the database since they likely worked for the other companies included therein. Yet, there may still be a hardy group of these possibly unrecorded investigators. Perhaps they only ever did one study, and that study was for a company without a marketed product. Or, for some reason these investigators restrict their activity to studies from quite small companies without a marketed product.

There may be 3% fewer study sites in Open Payments. Open Payments is, nonetheless, probably missing virtually no investigators looking to participate in further clinical trials.

Although there are two types of payments, general and research, this paper addresses research payments only. Research payments in 2020 constituted 74.6% percent of all the payment value in the total payment database containing both general and research payments. There may be many more individual general payments, but individual research payments are usually much larger. As we would expect, the total value of research payments in any given year is highly concentrated in the 20 largest pharmaceutical companies by spending volume (see Table 1). These companies may be found in Appendix A, listed by payment totals.

Table 1: Total 2020 Pharmaceutical Company Payments by Company Size as a Percent of all Pharmaceutical Company Payments

| 20 Largest Companies | 21 to 50 | 51 to 100 | Smallest Companies |
|----------------------|----------|-----------|--------------------|
| 74% | 17% | 5% | 4% |

Each research payment must be associated with a specific protocol and be covered by a written agreement between the site and sponsor. Certain research-related activities are reported under general payments, such as protocol development, data monitoring committee service, steering committee service, as well as meals and travel for investigators not covered in the clinical trial agreement. The research payments though cover only activities related to the conduct of clinical research itself, as covered in the clinical trial agreement. Individual research payment data provide the date and amount of the payment to clinical investigator and/or teaching hospital.

Only total payment amounts are reported for any individual payments. There is no way to disaggregate or allocate the total amounts for the individual payments into finer detail. Certain investigator and teaching hospital related data are associated with each payment, such as study name, sponsor company, investigator name and address, medical specialty, as well as the name and address of any institution associated with the payment.

There are operational challenges and limitations working with these data. First, the research payments data only cover U.S. investigators. Second, substantial data linking is necessary for the more than 6.5 million individual research-related payments in the database. The raw data do not show any grouping or linking by individual investigator, study, or any other variable. The linking process, followed by the authors, is better understood by demonstrating how payments and investigators are linked to the appropriate study. Each investigator does have a unique identification number in the database. Each payment can, therefore, be brought together with the appropriate investigator by that investigator's unique identifier. The major challenges come with connecting the individual payments, and hence investigators, to the correct study.

There is frequently very limited information in Open Payments about the individual study on which an investigator is working. There is usually only a study identification name and sponsor company name. From time to time there may be a National Clinical Trial number (NCT, assigned by ClinicalTrials.gov), but even then, this number may not be correct. The study name may be the same as that found in ClinicalTrials.gov, but this is rarely the case. The Open Payments study name may be some limited descriptive phrase, or something as simple as an internal company identifier. This identifier may consist of only a set of letters and/or numbers. In addition, the study name may be somewhat altered, or even spelled differently, in a subsequent year. The relevant pharmaceutical company name may also vary from year to year—one time it might be the U.S. operating company, the next year another unit of the same company. For instance, 15 different Boehringer Ingelheim entities made payments to investigators in that company's studies. More typical though is Eli Lilly, with three payment entities.

Extensive computer-aided reconciliation, along with substantial manual oversight, were necessary to successfully associate the various study names, company sponsor names, and individual investigator payments. The key steps are to:

1. Link individual payments to the individual investigator through the use of the Open Payments unique physician identification code.
2. Group the various payment entities to the correct parent organization. A pharmaceutical company may have multiple entities making payments in the same study, usually over a period of years. Or, the various subsidiaries may pay for entirely separate studies.
 - Strip the payment description of spaces and extra characters to insure an exact match within all the entries.
 - String matches across sponsored linked files to catch payments made across the sponsor's possible entities.
3. Connect the various physician payments to the correct study through the use of computer-aided programs (wizard pattern matching) and visual inspection. For any payment the correct study is initially determined by payment dates within the expected range, the unique investigator IDs, study name, and parent sponsor company name.
4. Through online searches, visual inspections, and specifically written computer programs tie the individual Open Payments study to the comparable study in ClinicalTrials.gov, providing far greater study design and execution detail. This is especially valuable to obtain more complete study titles than often found in Open Payments. However, in Open Payments, individual payment data rarely indicate the appropriate ClinicalTrials.gov NCT number.
5. Visually review all linkages using at least two observers, with any inter-coder disagreements resolved before the data are entered into the final database.

There are other important sources of clinical trial funding, most significantly the National Institutes of Health (NIH). Investigators active in NIH studies may or may not participate in pharmaceutical industry clinical trials; we have no way of knowing this from the Open Payments data. Open Payments data only cover industry-sponsored clinical trials, although some may be done in conjunction with the NIH.

Results

The level of pharmaceutical activity, according to ClinicalTrials.gov data (accessed on May 22, 2022), has remained essentially constant between 2018 and 2020. For instance, the number of pharmaceutical industry-sponsored Phase III and Phase II/III clinical trials begun each year shows little change between 2018 and 2020 (see Table 2). This is particularly noteworthy, given the very unsettled clinical trial environment during the onset of the COVID-19 epidemic.

Table 2: Number of Industry-Sponsored Clinical Trials Initiated Each Year

| | 2018 | 2019 | 2020 |
|----------------------|-------|------|------|
| Phase III and II/III | 1,053 | 948 | 999 |

It is not surprising then that the number of active U.S. PIs in any given year has also remained relatively constant. Since 2013, there have been 70,032 active, unique clinical investigators, with 83% working on pharmaceutical clinical trials. The remainder work exclusively on medical device studies. Many of the pharmaceutical clinical investigators were evidently inactive in recent years, while many new ones most certainly participated in their first clinical trial. From 2018 to 2020, the number of active clinical investigators was 45,554, again with 83% having worked on pharmaceutical clinical trials. The remainder of this paper concentrates only on data about investigators working on studies sponsored by pharmaceutical companies. Medical device studies are excluded.

The activity level within the various therapeutic areas may certainly change over time. However, the number of unique investigators participating in pharmaceutical studies is virtually unchanged from one year to the next; there is an almost constant number of unique investigators active in each year of 2018 to 2020 (see Table 3). Also worth noting is how closely the annual unique investigator number in 2020 (26,115) corresponds to the number of unique clinical investigators active in 2014 (28,292), the first full reporting year for the database.

Table 3: Number of Unique Active U.S. Clinical Investigators Participating in Pharmaceutical Clinical Trials Within Each Time Period

| 2013–2020 | 2018–2020 | 2018 | 2019 | 2020 |
|-----------|-----------|--------|--------|--------|
| 58,335 | 37,596 | 26,760 | 25,675 | 26,115 |

According to the Open Payments definition, there are more than 1,000 teaching hospitals in the United States. They receive about 17% of all payments, but a quarter of all payment value (see Table 4). This is hardly unexpected, since these institutions are much more likely to charge

overhead than private practice sites. In addition, hospitals will do a large portion of all inpatient studies, which are often among the most expensive.

Table 4: Distribution of Transactions and Total Payment Value in 2018–2020 by Type of Recipient Site

| Individual Payments | | | Payment Value | |
|---------------------|-----------|-----|------------------|-----|
| Private Practice | 1,296,664 | 83% | \$11,332,266,887 | 77% |
| Teaching Hospital | 258,772 | 17% | \$3,459,842,631 | 23% |

As indicated in Table 5, only 15% of clinical investigators work exclusively in teaching hospitals. Most conduct studies in private practice, or in a combination of private practice and teaching hospital settings.

Table 5: Percentage of Investigators Conducting Clinical Trials by Type of Site, 2018–2020

| | Teaching Hospitals Only | Private Practice Only | Both Hospital and Private Practice |
|----------------------|-------------------------|-----------------------|------------------------------------|
| Unique Investigators | 4,795 | 23,694 | 6,372 |
| Percentage | 14% | 68% | 18% |

Perhaps most striking is the study experience of most U.S. investigators described in Table 6. A high percentage of investigators (80%) have only done from one to five pharmaceutical industry-sponsored studies during the three-year period covered in this analysis. We include all industry-sponsored studies from Open Payments. Some studies may have recruited well, some may not have recruited as well. Some may have been terminated. We do know the date that each study began, based upon both the dates of that study’s initial payments and the comparable dates found in ClinicalTrials.gov for that study. The linked Open Payments data provides us with all

the investigators who worked on that study as determined by the payments data. The largest percentage of investigators (43%) have done only one industry-sponsored study. However, it is again worth noting that some of these investigators may have conducted studies for other organizations, such as the NIH. In some cases, then the clinical trial experience of individual investigators in Open Payments may be somewhat higher. Our data do not permit us to address that issue.

Table 6: Percentage of Investigators Conducting Pharmaceutical Clinical Trials by Number of Studies, 2018–2020

| 1 Study | 2–5 Studies | 6–15 Studies | More than 15 Studies |
|---------|-------------|--------------|----------------------|
| 43% | 37% | 16% | 4% |

There is a valuable distinction to be made between PIs who performed one study during this time period and the set of so-called “one and done investigators,” in that one and done investigators never do a second study. There could be a variety of reasons these investigators decide that they do not want to do a second study, including such considerations as the unanticipated increased administrative burden, the unexpected demands on professional staff, the added cash flow challenges, and a possible desire to focus on non-commercially funded studies. Perhaps, some of these sites should not have done even one study.

The number of the one and done investigators has been hard to establish. Some estimates have been as high as 50%.^{2} However, these percentages have often come from the Bioresearch Monitoring Information System (BMIS). Companies are required by the FDA to obtain a completed Form 1572 (Statement of the Investigator) from each investigator in their study. This form provides the investigator’s professional credentials. Sponsor companies are also required to provide the FDA with the curriculum vita on each PI in their study.

Often, sponsor companies chose to provide the completed 1572 to meet the curriculum vita requirement. However, sponsor companies are not required to submit the completed 1572 to the FDA, only to maintain it in company records. As a result, companies often do not submit the completed 1572 form to the FDA.

Hence, the BMIS dataset is simply not a complete database of active clinical investigators. In fact, the FDA states on the website, “BMIS is not intended to provide a comprehensive list of all clinical investigators.” For many years though, public 1572 records were the best publicly available source of data about investigators. In marked contrast, Open Payments now covers a near census of U.S. investigators and their clinical trial experience.

The actual percentage of one and done U.S. investigators participating in pharmaceutical industry clinical research is 20.3%. That is, in any given year about a fifth of active investigators will only ever do one pharmaceutical company-sponsored clinical trial. The authors used 2018 as the base year, determining all the unique investigators whose names (and unique identifier numbers) appeared on one study and never appeared on a second study through the end of 2020.

Similarly, we examined the two years preceding 2018, that is 2016 and 2017, to establish if that investigator’s name appeared in a previous study during those preceding two years. Only investigators who took part in one study in 2018, but in no other study in 2016, 2017, 2018, and 2019, were deemed to be a one and done investigator.

At the other end of the activity continuum, we see in Table 7 that clinical trial activity is highly concentrated. A relatively few investigators take part in many clinical trials.

The actual total amount of clinical trial activity associated with each experience category, then, is dramatically reversed when looking at the site activity level within each of these experience categories. For example, while only 20% of all sites have taken part in six or more studies between 2018 and 2020, these sites represent two-thirds of all clinical site activity. In other words, many sites do only a few studies (five or fewer). On the other hand, a few sites do many studies.

Table 7: Percentage of All Clinical Site Activity by the Pharmaceutical Clinical Trial Activity Categories, 2018–2020

| 1 Study | 2-5 Studies | 6-15 Studies | More than 15 Studies |
|---------|-------------|--------------|----------------------|
| 10% | 25% | 33% | 32% |

Conclusions

Several conclusions arise from this analysis. At the macro level, the U.S. clinical investigator terrain has experienced little change. The number of active investigators remained constant for the years examined, even if the therapeutic composition of studies probably varied over time. Moreover, the number of investigators is virtually the same as in 2014. The overall demand for investigators has clearly remained steady. Any claims that the demand for clinical investigators has grown by any significant degree is belied by actual data.

Second, most investigators have little clinical trial experience. A high percentage of U.S. clinical investigators participated in only one study during the three years covered by this study. More than three-quarters of all U.S. investigators took part in five or fewer clinical trials between 2018 and 2020. Moreover, in any given year about 20% of investigators who do their first study never do a second one. This constant search for investigators must present drug development operations with high monetary and opportunity costs. Certainly, a significant portion of the resources devoted to finding and training investigators could be better employed if the investigator identification process were improved.

A relatively small number of U.S. investigators take part in a very large percentage of all the studies, perhaps even when they are not necessarily the best suited to enroll patients for these trials. A major advantage in some cases for these sites is simply that they are known to sponsors.

Our research team is presently examining a number of related topics, including more granular analyses for future publication. For instance, do the results vary by such considerations as physician specialty, or whether a physician is based in private practice or teaching hospitals. Further, and perhaps most intriguingly, we are looking at how well the total amount of payments

an investigator receives in a given study correlates with the actual number of patients that investigator enrolled. In other words, can payment totals, in some form, be a surrogate measure for comparative enrollment performance?

The raw data in Open Payments constitute a major data-linking challenge. However, when properly aggregated and connected to ClinicalTrials.gov, the data in Open Payments offer a number of potential benefits to clinical operations professionals. For example, sponsor management can move beyond investigators selected chiefly because they are known. The data should also help reduce churn through large numbers of inexperienced investigators.

Open Payments contains the name, telephone numbers, and addresses of virtually every active clinical investigator participating in industry-sponsored trials since the end of 2013. Moreover, it is possible through data-linking to obtain a detailed understanding of almost all of the studies that each of these U.S. investigators worked on during that time. That is, there is an activity and performance profile for almost all of the active U.S. investigators. Similarly, it is possible to start from the aggregated, study-specific information to determine all the investigators who worked on that given study. That is, there is a detailed study profile for almost all of the industry-sponsored studies. It may even be possible, using payment levels as a surrogate measure, to come up with how well an investigator has enrolled in a study compared to all the other investigators in the same study.

At the same time, clinical operations management can develop company-specific benchmarks. With Open Payments, they now have access to data on U.S. investigators' performance on studies sponsored by all the other pharmaceutical companies with one or more marketed products. Benchmarking examples might include whether some companies select more experienced investigators than others, and whether these are the better enrolling investigators. Further, if a company maintains an internal clinical trial operations capability and uses contract research organizations, does the experience and performance profile vary by the various clinical operations organizations? Are some companies better than others at avoiding the use of one and done investigators? The data now exist to answer these questions.

Open Payments data can at least answer questions regarding who the active U.S. investigators are and what studies have they actually worked on. The clinical trial management implications of the answers to these questions can be significant, particularly if the individual investigator data can be tied to validated surrogate performance measures, based upon payments, for all the investigators in a particular clinical trial.

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Harold E. Glass, MSc, PhD, (hglass@healthresearchinst.org) is a Co-Founder of [SunshineMD](#), a site selection consultancy firm, a retired Dean's Professor with the University of the Sciences, and former President and CEO of TTC-LLC in Philadelphia, Pa.



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Appendix A

Largest 20 Pharmaceutical Companies by Volume of Open Payments Spending

PFIZER
NOVARTIS
MERCK & CO.
GENENTECH/ROCHE
ASTRAZENECA
AMGEN
ELI LILLY
BRISTOL MYERS SQUIBB
ABBVIE
JANSSEN
SANOFI
ALLERGAN
GILEAD SCIENCES
GLAXOSMITHKLINE
REGENERON
NOVO NORDISK
TAKEDA PHARMACEUTICALS
CELGENE CORPORATION
BIOGEN
INCYTE CORPORATION

SPECIAL FEATURE

Innovate to Increase Diversity in Cancer Clinical Trials

Arturo Loaiza-Bonilla, MD, MEd



The fight for fairness and equity in medicine took a dramatic step forward last June, when the U.S. House of Representatives passed legislation intended to increase the racial and ethnic diversity of patients enrolled in clinical trials of new drugs. The proposed law would require sponsors of clinical trials to develop and submit diversity action plans describing their goals and strategies for achieving demographic equity in Phase III studies of novel therapies.

Lack of diversity in clinical research is not a new problem; the U.S. Food and Drug Administration (FDA) has periodically issued guidance calling for greater inclusiveness in clinical trials since 1988. However, while new regulations and incentives for sponsors may help, no negative actions have been taken in the FDA’s oncology review divisions in cases of sponsor failure to conduct more diverse trials, and vague diversity guidance continues to raise concerns.

Lola Fashoyin-Aje, associate director of the FDA Oncology Center of Excellence and deputy director of the Center for Drug Evaluation and Research’s Division of Oncology III, said that the agency recognizes clinical development does not stop at application approval, adding that in some cases more studies may be necessary if diversity targets are not met.

“There may be circumstances where it is appropriate to do post-approval studies,” Fashoyin-Aje said after a session on enhancing clinical trial diversity, equity, and inclusion at the [National Organization for Rare Disorders Breakthrough Summit](#). “Part of that will include understanding why we fell short. We will learn about what works and doesn’t work.”

Indeed, the global life sciences industry has much to learn to bridge the diversity divide in cancer clinical trial participation. The good news is advanced technology can help—it's time to leverage such modern innovations as artificial intelligence (AI), digital tools, and analytics software to move the needle.

The Extent of the Problem in Oncology Research

Black people are significantly more likely to die of many forms of cancer than white people. Yet, while about 15% of cancer patients in the U.S. identify as Black or African American, they make up just 4 to 6% of participants in trials of investigational cancer therapies. Similarly, 13% of cancer patients identify as Hispanic or Latino, but that's true of just 3 to 6% of enrollees in oncology trials. These figures may be even lower, since fewer than one-third of cancer trials report race and ethnicity data.{ 1 }

These disparities contribute to the larger problem of social injustice in medicine, which was highlighted by the COVID-19 pandemic's disproportionately cruel impact on communities of color but has persisted in the delivery of healthcare in the United States for millennia. What's more, underrepresentation in clinical research is bad for medical science, since it frequently means that the racial composition of a patient cohort in a trial doesn't mirror the disease burden in the real world and, consequently, the resulting therapeutics are not always equally effective for all demographics.

Black Americans are [underrepresented in 85%](#) of clinical trials—by a lot.{ 2 } In a study published in *Health Affairs* last March, researchers began by compiling data on the portion of Black patients included in each of 225 pivotal trials (cancer trials made up more than one-third). Next, they looked at the general population of people who have each of the diseases treated in these studies and identified what percentage of these patients is Black. Comparing the two sets of data showed that the representation of Blacks in clinical trials was about one-third of what it should have been to reflect the diversity of patients who have each disease studied.

That’s a serious flaw in a study’s design. Underrepresentation of a demographic group in a clinical trial can fail to reveal a benefit or risk that an investigational therapy may have for a given demographic group, since it’s well established that [race and ethnicity can affect the pharmacokinetics and pharmacodynamics](#) of a drug, and thus its safety and effectiveness. There are many examples of this phenomenon—for instance, doctors avoid prescribing ACE inhibitors to Black patients, who tend not to respond well to these blood pressure medications.

Nowhere is this more impactful than in cancer, where there are more diagnoses now but lower mortality rates (the death rate from cancer fell 32% between 1991 and 2019) presumably due, in part, to an increase in novel treatments and clinical trials. Fortunately, it appears that the industry is passionate about rectifying this pervasive problem, but it’s not going to be easy. Good intentions, and even regulatory changes, may not be enough. A true fix must address many multifaceted hurdles.

“We can improve population representation in cancer clinical trials by investing in the education and recruitment of more diverse trial investigators,” said Elena Rios, MD, MSPH, MACP, president and CEO of the [National Hispanic Medical Association](#). “Hispanics and Latinos [make up] about 19% of the U.S. population, yet less than 7% are physicians and less than 1% work in academic facilities. Hispanic clinicians tend to attract patients from their own communities. If more Hispanic clinicians were involved in clinical research, naturally, more of their Hispanic patients would participate in their trials.”

Hurdles to Overcome

Why is it such a challenge to establish equitable participation of people of color in clinical trials? It’s a complex question that lacks easy answers, but some factors include:

- **System Mistrust**—This is an unfortunate legacy of past research abuses such as the infamous Tuskegee Syphilis Study, in which Black men who had the sexually transmitted disease were recruited to participate, but never offered treatment. In several studies, Black people told investigators they believed that patients in clinical trials were “guinea pigs.”{2}

- **Clinician Bias**—A recent joint statement{1} on the need to increase racial and ethnic diversity in clinical trials from the American Society of Clinical Oncology (ASCO) and Association of Community Cancer Centers cited clinician bias as one barrier. “Clinicians may believe people from racial and ethnic minority populations will be unwilling to enroll or unable to comply with trial protocols,” the authors speculated. Finding the right clinical trial for each cancer patient takes a lot of time, too, which many oncologists lack. Further, a new [paper](#) presented at ASCO’s annual meeting in June found that 40% of Black patients with metastatic breast cancer said that no one on their healthcare team mentioned the possibility of enrolling in a clinical trial versus 33% of White patients.
- **Financial Barriers**—People from underserved communities tend to have lower socioeconomic status, making it difficult to cope with costs associated with participating in a clinical trial, such as travel and lodging expenses. Most recently, decentralized trials are helping to offset these issues. Hybrid trials—combining a mixture of site-based and decentralized solutions—make it possible to conduct aspects of the trial remotely, supporting a better patient experience and increasing access to trials while still conducting the aspects that require in-person interactions.
- **Lack of Clinical Trial Awareness**—Low health literacy [disproportionately affects](#) Black Americans, and studies have found that levels of knowledge about clinical trials are lower in communities of color whereas education about trials has been shown to increase willingness to participate.{2}

“Our foundation is building a network of Hispanic and Latino clinicians running clinical trials as well as educating and promoting the profession of researcher to young residents,” explained Dr. Rios. “We do this through scholarship, mentoring, and annual meetings in conjunction with the [National Institutes of Health] to foster research skills and passion for research. In the end, it is these physicians who will be instrumental in promoting trial participation in their local communities.”

- **Restrictive Inclusion/Exclusion Criteria**—Oncology trials are notoriously stringent in their participation criteria. In fact, 40% of patients with cancer trials available to them are not eligible to enroll due to eligibility requirements, according to a [report](#), and there can be an unintended bias.{3} For instance, Blacks are more likely to have comorbidities,

such as cardiovascular disease, that prevent them from enrolling in clinical trials due to stringent exclusion criteria. While these criteria are intended to ensure patient safety and create a homogenous study cohort, they may be too rigid. The U.S. National Cancer Institute (NCI) concluded that eligibility criteria arbitrarily eliminate patients and should be simplified and relaxed.

The Biggest Hurdle of All—And How to Overcome It

Arguably, the biggest barrier to fair representation in cancer trials is the disconnect that exists between where most cancer trials are conducted and where most patients live.

Across the United States, 71 NCI-designated cancer centers perform novel oncology research. Most NCI-designated cancer centers are affiliated with academic medical centers, which tend to be in large urban centers. While the contributions of these hotbeds of oncology research can't be overstated, they serve a minority of cancer patients. Of the 1,700,000 Americans diagnosed with cancer in 2021, only about 15%, or [roughly 255,000, were treated at NCI-designated cancer centers](#). The other 85% received care at community-based practices.{4} This means that the NCI-designated sites with breadth of knowledge and experience in conducting clinical trials serve relatively few patients while community-based practices with huge volumes of patients handle very few trials.

As an industry, we can dramatically improve diversity in trials if we recruit from the entire community of cancer patients instead of a select group that happens to have the geographical advantage of living near an NCI-designated site. New technology, driven by AI and powerful algorithms, can help cancer patients and their clinicians rapidly identify trials that aren't necessarily being studied at the clinic down the road, but that could add years to their lives. In fact, SYNERGY-AI is an innovative platform that uses AI to extract information automatically from patients' electronic health records, including biomarker and other test results, and quickly identify cancer trial matches. The platform has [onboarded more than 102,000 patients](#) since 2020 with an additional 6,000 patients every month.{5}

“AI and machine learning technologies can play a major role in identifying both patients and clinicians of color,” according to Dr. Rios. “It would help more, though, if it were no longer optional to notate your ethnicity in healthcare records. We need to track ethnicity for everyone so it’s easier to find diverse patient pools and oncologists. We know where doctors work, but we don’t always know their ethnicity.”

This seemingly simple approach is now feasible with the advent of decentralized or hybrid trials which makes geography less of a non-starter for trial participation. Increasingly, investigators leveraging these trial models allow patients to participate largely from their own homes by supplementing site visits with digital alternatives such as telemedicine, wearable devices, smart apps, and direct delivery of study drugs and materials to patients. These trials are not only faster and more efficient than traditional trials where patients must report regularly to a clinical site, but also more democratic and inclusive.

The Bloomberg New Economy International Cancer Coalition brings together academia, industry, government, patient advocacy and policy think tanks to leverage technology and collaboration to improve patient access to clinical trials and to harmonize regulations aiming to accelerate cancer cures and prevention worldwide. The coalition members convene regularly to explore ways to achieve better access to clinical trials, and one conclusion is that “innovations in information technology should be part of the solutions to overcoming many of diversity barriers.”

When it comes to cancer patient matching, the coalition agrees:

Specifically, with clinical information entered appropriately into an electronic health record during routine care, the central registration and trial management software can systematically identify patients and match them to trials based on the molecular features of their tumors and other eligibility criteria. Efforts should also be put toward increasing awareness of biomarker testing through physician and patient education, as well as decreasing barriers to access through infrastructure improvement and the adoption of new technology.

The technology is here today that can help finally overcome many of the biggest barriers to population representation in cancer clinical trials, but it takes more than just technology. As we get excited about the potential promise of AI and analytics-based solutions, it's just as critical to help patients through that last mile in trial enrollment. Companies that provide high-touch care for patients who are often overwhelmed by trials and, at the same time, exhausted by the side effects of their treatment and disease. In this “last mile,” one-on-one patient handholding can also serve to sensitively identify and eliminate any unanticipated participation barriers, such as travel logistics and costs, and maintain their active engagement until the very last dose of their investigational treatment.

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The Difference Between Data, Metrics, Reporting, Analytics, and Insights

Chris Bryant



The words data, metrics, reporting, analytics, and insights are frequently used interchangeably by organizations while assessing a meeting's results to inform future meeting planning. Knowing the distinction between these terms, however, can be the difference between analysis paralysis—a state of stagnation caused by too much raw information—and the evolution of meetings into strategic tactics that generate business opportunities.

Data: collected information, ranging from demographics to engagement during the meeting

Collecting data from the audience is a fundamental part of every meeting, whether it is an intentional process or not. Data are collected information, ranging from the most basic action to complex engagement. Data are generated when someone interacts with anything on a webpage, such as a button click or typing in a message. For example, datapoints could be the time the action happened or who took the action. At this stage, the data are uncategorized and only form the foundation for further analysis. Often, these data are collected, stored in a spreadsheet that is disorganized or difficult to parse, and inevitably forgotten or lost.

Data collection serves as the basis for all the other steps in this process. Raw data don't mean much, but there are ways to measure these data against goals, which leads to the next important piece of meeting strategy: metrics.

Metrics: pieces of collected data that help measure against a stated goal

Metrics and data are similar, but with an important distinction: while data are random pieces of information (and therefore difficult to use on their own), metrics are data that are measured against a stated goal. While they differ across different types of meetings, goals often relate to things such as attendance, revenue generation, knowledge transfer, feedback collection, alignment, or any number of other organizational priorities. Turning data into metrics is a way to separate the useful information gathered during meetings from the noise.

Going into your meeting with the end goals in mind (i.e., the percentage of audience engagement you would like to achieve, or the percentage of knowledge transfer required for your session) gives you a tangible starting point for improving your meetings. Since metrics tell you exactly how closely the meeting or meetings met your goals, it is simple to start to create an updated strategy for the future.

However, even if you are only collecting the most relevant data to measure against your goals, metrics are still unstructured and can make the average meeting organizer's or executive's eyes glaze over. Reporting can make metrics more easily digestible.

Reporting: an organized collection of data and metrics

Reporting is a way to organize and communicate the data and metrics you collect. Reporting can take a variety of forms, such as a spreadsheet with ways to filter the data, or it can be more visually compelling with graphs and charts. However, not all reporting is created equal. If the reporting is difficult to read or doesn't contain the context of the goals for the meeting, the odds of you being able to gain any actionable insights from it are slim.

If the reporting is organized well and reflects how far you are from the goals you set, the patterns should be more easily identifiable, paving the way for analytics.

Analytics: a summary of patterns within collected metrics

The term analytics refers to patterns that are identified within collected data and metrics. This requires digging into the reporting and revealing aggregate information, comparisons between

data, benchmarking, and other analyses. Of course, choosing the right combination of metrics to analyze requires an understanding of what insights you want to reveal.

For example, metrics can show what content produced the most engagement interactions. If a goal of the meeting is to understand whether a gap in knowledge has been corrected, then these interactions must be filtered by attendee type to reveal opportunities to address and refine that content. By adding metrics as to which presenters were most effective and comparing that to correct answer scores on the topics, you could also identify potential opportunities for presenter training.

There are even technologies that can parse datasets and reveal patterns and analytics. However, the next step, translating analytics into actionable insights, requires a more human touch.

Insights: thought-provoking outcomes that lead to possible new courses of action

Insights take the data a step further than analysis by answering such questions as “So what?” or “Why is this important to my business?”

Knowing that 90% of people answered a polling question correctly is useful. However, an insight might indicate that you need to restructure part of a presentation because the 10% who got it wrong all made the same mistake, indicating that something they saw or heard caused the confusion. If confidence levels in answering that question have been measured, then analysis may show a group of participants who answered incorrectly but were extremely confident—and therefore have likely been misinformed. Appropriate follow-up would be to assess who falls into this category and address that potential misinformation directly, or *en masse* if appropriate.

Insights should be paired with action. If your analysis of the data doesn’t prompt you to take steps to progress and/or improve, then it’s not doing you any good.

Insights come from pulling actionable steps out of the analytics of your meeting data. Actionable steps are those that can be used to immediately improve your meetings, such as finding a knowledge gap based on polling responses that you can then pay extra attention to at a future session or point out in a follow-up. You might also obtain insights into information about how

well you achieved your meeting goals, how engaged your audience was throughout, the breadth of your participant demographics, and what all those things mean for your meeting structure, audience satisfaction levels and evaluations, and more. Insights are the best way to take your meetings to the next level, since they provide you with immediately concrete and implementable steps that can improve meeting experiences for you and your attendees.

Conclusion

With a better understanding of the distinctions between data, metrics, reporting, analytics, and insights, and of how to use each to its greatest extent, meetings can become truly strategic resources for life science organizations.



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SITES & SPONSORS

Laying the Foundation for Integrated Evidence

Lauren Sutton, MBA; Neal J. Meropol, MD



A recent analysis of U.S. Food and Drug Administration (FDA) drug approvals between 2010 and 2020 indicates that the median time from initiation of clinical testing to licensing is 8.3 years.^{1} A significant amount of data needs to be collected over a lengthy period in order to generate meaningful evidence to bring new therapies to patients. The time spent at clinical research sites to collect these data slows down the ability to generate evidence on benefits and risks, and there is a critical unmet need to

develop new solutions to support data collection that could improve the speed and efficiency of clinical research.

It is notable that much of the data collected for clinical trials represents standard practice for the particular clinical condition. Thus, one might consider two types of data relevant to clinical research, based on the core reason for their collection:^{2,3}

- 1. Routinely collected data (also termed “secondary data” for clinical research):** Data that are generated during a clinician’s encounter with a patient and are commonly documented within the patient’s electronic health record (EHR) during routine clinical care.
- 2. Intentionally collected data (also termed “primary data” for clinical research):** Data whose collection is above and beyond what would otherwise be collected as a part of routine practice. These parameters that are required by the clinical study protocol may include data elements that are not part of routine care at all, or might be routinely collected but the protocol specifies some aspect of their collection (e.g., specific interval for certain clinical assessments such as radiographic imaging or diagnostic blood tests).

Most routinely collected data are captured within the EHR, while most intentionally collected data are still captured on paper forms that are stored at clinical trial sites within “paper shadow charts.” Technology providers are now developing new methods that make it easier for clinical research sites to capture intentionally collected data, such as:

- **Point of care workflows** enabling the prompting of intentionally collected data by clinicians and research teams directly within the EHR.
- **Text note templates** (i.e., data collection forms embedded in the EHR) making it easier for clinicians or study staff to capture intentionally collected data during a patient’s study visit.

There is industry momentum for adopting these new methods for the capture of intentionally collected data at the point of care, leveraging the EHR. As we saw in the FDA guidance published in July 2018 on the Use of Electronic Health Record Data in Clinical Investigations,{4} the agency specifically calls for two foundational changes to clinical research:

- 1. Research workflows built within EHR systems** to capture intentionally collected data at the point of care.
- 2. Data from the EHR being used to drive downstream efficiencies** in the overall execution of clinical research studies, reducing dependence on manual data transcription from the EHR into study electronic data capture (EDC) systems.

Research Workflows Built Within EHR Systems

The clinical research team at Flatiron Health spent more than 150 hours with many community oncology sites, conducting in-depth user research to better understand how research teams typically capture intentionally collected data. Among the many pain points that were identified, the most common feedback was that there are challenges with knowing which data to capture at which time points and for which patients.

The increasing complexity of oncology clinical trials is exacerbating the data collection burden, leading to stressors on the clinical research workforce.{5} Research teams are often running many clinical studies, all with different expectations and guidance on data collection, and it is difficult to keep track of each individual study’s requirements. As workarounds, site research

teams may create paper templates, logs, and worksheets to help them remember which data need to be collected for each study visit.

In response to FDA guidance, industry imperatives regarding efficiency, and site research workflow challenges, we have identified an opportunity for EHR systems to support the capture of intentionally collected data at the point of care. Rather than site research teams creating separate workflows to capture data for the studies they are supporting, there are ways that the EHR can be configured to support specific study use cases.

If the EHR is able to help research teams know what data to collect for which patients and at which timepoints, this could significantly alleviate the burden placed on site research teams to navigate data collection and enable them to spend more time with their patients. Technological advances related to protocol digitization (the structuring of data collected for a clinical study) will help EHR systems have a blueprint for the data that need to be collected for patients participating in clinical research. This will enable workflows to be built that capture intentionally collected data using EHR-embedded forms directly at the point of care.

Data from the EHR Being Used to Drive Downstream Efficiencies

Integrating intentionally collected data variables into the EHR unlocks the opportunity for automated transfer of study clinical data from site EHR systems into sponsor EDC systems, increasing site efficiency, improving accuracy of data by eliminating manual transcription, and accelerating the delivery of data to study sponsors. There are applications on the market today that facilitate this automated data transfer. These applications take data fields from the EHR system and map them to the underlying data model for the study EDC system.

Regulations, such as one tied to the Office of the National Coordinator for Health Information Technology's Certification Program within the 21st Century Cures Act^{6} that requires EHR systems to adopt Fast Healthcare Interoperability Resources standards, have laid the foundation for a common data standard amongst EHR systems to create solutions that enable this data transfer at scale.

Much of the data that exists within this common data standard is routinely collected data, and typically does not include intentionally collected data. Incorporating intentionally collected data into “EHR to EDC” solutions requires complex mappings between EHR point of care workflows where data are captured and downstream EDC systems that receive these data.

Exciting advances in drug discovery have the unintended consequence of adding stress to an overburdened clinical research infrastructure. Fortunately, we now have technologic solutions to support the imperative to generate evidence to expand treatment options for patients. As displayed in Table 1, these technology solutions introduce benefits to both sites and sponsors.

Table 1: Benefits of Technological Advancements to Sponsors and Sites

| Sponsors... | Sites... |
|--|---|
| <ol style="list-style-type: none">1. receive higher quality data with no manual transcription errors.2. are enabled for faster decision-making due to receiving data faster from sites.3. enjoy cost savings due to reduction in review of manual transcription (source data verification).4. can create less burdensome trials, thus increasing a trial’s attractiveness to competitive sites. | <ol style="list-style-type: none">1. enjoy a reduction in time needed by research coordinators for initial data entry from EHR system into EDC system.2. can eliminate the time it takes to respond to data queries in the EDC system due to transcription error.3. are able to spend more time with patients and less time on operational tasks. |

Conclusion

Like any clinical investigator, technology product developers for mission-driven health organizations should have the goal of accelerating the development of new therapies for patients. We believe that incorporating intentionally collected data capture at the point of care within the EHR and automating its transfer into EDC study databases will be instrumental in achieving this goal. It is important that solutions that augment data capture at the point of care are optimized for clinician and research staff workflows and designed in a way that lessens operational burden.

While initially designed as communication and documentation tools for clinical care and reimbursement, the EHR is now increasingly recognized for its potential in clinical research. Leveraging these capabilities can fundamentally redefine how the collection, aggregation, and delivery of clinical study data contribute to integrated evidence generation.

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TRIALS & TECHNOLOGY

The Right Tools for the Job: Deploying Technology to Overcome Major Challenges in Early-Phase Research

Brad Vince, DO



Phase I clinical trials are unique in the drug development process in that they require overnight confinement of study participants to a research facility for days and sometimes weeks at a time. Furthermore, instead of patients who are afflicted with the disease or condition being studied, Phase I trials typically use participants who do not have any significant medical conditions, known as “normal healthy volunteers.” Lastly, while late-stage trials have flexible windows for study visits and procedures, Phase I trials are the exact opposite; their visits follow narrowly defined schedules, and their procedures must be performed at exact timepoints relative to the administration of the investigational product, all of which adds up to a very labor-intensive process. These stringent requirements give rise to unique challenges during Phase I study conduct.

Perhaps the most significant challenge that contract research organizations (CROs) face when conducting Phase I trials is the lack of updated, purpose-built facilities for them. In many cases, Phase I sites are placed in antiquated buildings that have been repurposed to conduct early-phase trials. Unfortunately, these facilities do not invite the same level of innovation or efficiency found in modern building design and construction.

Fortunately, even the most outdated buildings can benefit from several innovative modalities that can propel them into the modern era of research. The following is an overview of challenges faced in early-phase studies and the corresponding technologies that help overcome and eliminate these issues.

The Quality Conundrum

Many clinical research sites still utilize paper source documents, recording data manually and then transcribing it into a database sometime later. At minimum, this presents two instances where manual entry can cause data errors. What's more, if there is a mismatch between the information captured on the source document versus the information entered in the database, a query may be issued. Given the large number of datapoints captured in a Phase I study, query resolutions can cause considerable delays in achieving database lock, which will impact the timeline of nearly every downstream deliverable.

Phase I CROs should consider leveraging an electronic source (eSource) platform to significantly reduce the potential for error by automatically transcribing the data into a database. This technology can save even more time and yield even more powerful insights when integrated with additional equipment, such as vital signs machines, ECGs, and barcode scanners. When properly deployed, this equipment allows real-time transcription with no manual data entry or human calculations of any kind. This can significantly reduce the time spent on query resolution and provide even greater efficiencies when trial investigators can review and sign off on data remotely at any time of day.

The Paper Trap

Continued reliance on paper documentation creates numerous issues that cause challenges for research sites across the board. Paper records require wet ink signatures, which can create a bottleneck for completing study-related activities and require the documents to be physically stored onsite for the duration of the trial and beyond. Again, this invites the possibility of human error when records are moved or modified, creating a significant obstacle in producing complete datasets and finalizing trial closeout activities. Furthermore, when the time comes to monitor your data, tracking down paper records for clinical research associates requires significant resources that could otherwise be used to support clinic activities.

To solve these issues, Phase I sites should adopt a digital and cloud-based investigator site file for document management. These systems offer signatures that are compliant with 21 CFR Part 11 in the *Code of Federal Regulations* for long-term records with remote monitoring and the

ability to automatically redact specific parts of documents to maintain blinded data and participant privacy during sponsor review. In addition, all document audit trails can be reviewed and downloaded.

The Trouble with Temperature

Early-phase trials often require extensive onsite storage for investigational products (IPs) and pharmacokinetic samples collected from participants. Storage requirements are outlined in established procedures, pharmacy manuals, and laboratory handbooks, and they specify the acceptable ranges that still allow for taking precise measurements, such as those for the temperatures found in freezers, refrigerators, and ambient spaces. If these environmental settings fluctuate outside the permissible ranges, drug products and samples could be rendered unusable, resulting in unnecessary waste and additional delays to trial activities.

To prevent significant excursions, 24/7 cloud-based environmental monitoring should be utilized in all pharmacy and sample storage areas, as well as in temperature-controlled equipment. The most effective environmental monitoring platforms will send alerts to relevant site staff via phone calls, text messages or e-mails, and these alerts will be accessible remotely from any browser or web-based application. Typically, a dashboard will provide an overview of all environmental conditions being tracked, displaying real-time readings and graphical representations of the data gathered by each sensor over time. Best of all, these platforms allow for 21 CFR Part 11–compliant data logging with clear audit trails and secure user access.

Inventory Management

As labor-intensive as Phase I trials are, they also require large volumes of supplies and materials. A Phase I site must avoid inadequate or expired inventory at all costs, as either scenario can be problematic for a study. Using expired test tubes can result in protocol deviations, potentially compromising study data and demanding attention through a corrective and preventive action (CAPA) plan. As such, having a system in place to provide visibility into inventory levels and track lot numbers and expiration dates is of considerable benefit to both the site and sponsor.

The Little Things Matter

Often, the adoption of technology in clinical pharmacology studies has been resisted due to caps on capital expenditures, limited overall budgets, and a lack of adequate training. The unfortunate truth is that many facilities are not profitable enough to fully invest in technology, and even if the funds were available, post-pandemic realities coupled with the strain of the “Great Resignation” has created an environment where clinical research sites are too busy and too short-staffed to challenge the status quo. As a result, systems in clinical pharmacology studies will remain antiquated as long as “good enough” remains the prevailing mentality across Phase I sites.

Fortunately, sites do not need to make substantial investments across the board to improve their operations. The little things matter, and minor expenditures can have a significant impact on a site’s results. For example, having the technology to contact study volunteers via their preferred method of communication, such as a text message, can decrease no-show rates for study visits. Transitioning a participant database away from spreadsheets to a cloud-based system can allow investigators to make real-time updates. Biometric security controls for pharmacy areas can help ensure that IPs are not handled by anyone other than approved staff.

Implementing these functions is fairly cost-effective, and training researchers to use them is quick and easy. Ultimately, small updates like these can alleviate the burden on staff and better optimize their time. In doing so, Phase I sites may find it possible to make even greater investments with a truly meaningful impact on clinical pharmacology studies as they progress into the future.



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RECRUITMENT & RETENTION

Technology Advances *How We Design Clinical Trials: Wearables, Devices, and Data*

Wessam Sonbol, CSM, CSPO, ICP-ACC



In the June 2022 *Clinical Researcher*, [we discussed](#) how the clinical research enterprise embraced newer technology solutions more quickly than usual due to the challenges the COVID-19 pandemic forced us to overcome in order to keep clinical trials moving forward.

In just the short time since that article, clinical researchers and study teams around the globe have widely adopted technology solutions that will forever change how clinical trials are designed and conducted moving forward. Sure, traditional clinical trials are still being conducted in person, but simultaneously virtual, decentralized, and hybrid clinical trials are also growing in numbers—removing geographical boundaries for patient participants, which has led to a much-needed increase in patient diversity, too.

As with any new frontier, we get excited about the progress that has clearly been accomplished and about continuing to push ahead toward the positive gains. However, with all the good strides we have taken as a field, it is important to also hear, acknowledge, and adequately address the concerns of clinical researchers and patients alike when moving forward. Here are a few observations we've made these past few months in the field, as well as some strong technology solutions we've been able to see proposed, created, or implemented along the way.

The Rise of eConsent

Electronic informed consent (eConsent) platforms are advantageous and generally easy enough for sponsors and sites to implement into their day-to-day operations. These tools bring value for all stakeholders, including patient participants, within the process through the following effects:

- Reduced burdens from paperwork for clinical trials staff and its storage implications, which leads to greater accuracy and efficiency—saving time and money;
- Simplified informed consent processes for participants, which boosts patient engagement overall;
- Provision to sponsors in real time of patient participants' consent data, supporting the study management and regulatory processes.

eConsent is a game-changer because patients will have the opportunity to be informed by different means, like video and/or audio clips, graphics, examples, hyperlinks, etc. The multimedia interaction is even accessible via the patient's own device (e.g., smartphone, tablet, computer, etc.). This accessibility allows patients to take the information home, via their personal device, and discuss with family and friends—and even do some additional research, if they wish—all from the same device without any additional equipment.

It should be noted that this multimedia approach can also overcome language barriers and impairments. For example, videos can be pre-recorded in multiple languages, including sign language for those potential patients who are hearing impaired. For patients who are vision impaired, audio messages can also be recorded in abundant, verbal detail to meet their needs.

The interactive presentation of the study procedures and commitments should make the informed consent process not only easier to understand, but also more comprehensive.

The Widespread Adoption of Wearables, Biosensors, and Other Devices

Wearables are being implemented in more and more clinical trials, and gaining steam in the healthcare world at large. Deloitte [predicted that 320 million](#) consumer health and wellness wearable devices will have shipped worldwide in 2022. Among other benefits, these devices

enable a clinical study team to monitor their patients' various health metrics, like daily steps, sleep quality, and heart rate, thereby increasing patient compliance and retention.

The most advanced wearables offer a customizable technology solution to researchers and providers, opening up a whole new world of possibilities for captured data that can be used to enhance patient outcomes and care delivery.

Over the next 25 years, wearables are expected to reduce healthcare costs by *more than 20 billion dollars*, providing more accurate insights into patient activity. The quality data collected and analyzed by these technology platforms can help researchers and providers gain a better perspective on *why* a certain implanted device might be acting a certain way, or whether a treatment has changed a patient's daily activities.

While there are a lot of pros to using wearables, biosensors, and other devices in your upcoming clinical trial, we understand there are some challenges that come with implementing new technologies. Collecting, standardizing, and validating the data, which are necessary precursors to data analytics, can be a challenge for many health systems.

Technology Allows for Decentralized Operations, But Logistics Still Matter

Virtual clinical research organizations (VROs) still need to consider the logistics when implementing virtual and hybrid clinical trial designs. Those who have true end-to-end solutions have the infrastructure in place to ship and deliver wearables, biosensors, other devices, pharmaceuticals, etc. for use in clinical trials around the globe. A sufficiently agile clinical study team should be able not only to technologically integrate with virtually any wearable, but also to:

- procure devices;
- collect the patient data;
- reconcile and analyze the data; and
- report the analytics—in *near* real time.

Technology solutions streamline patients' data collection in order to not only increase the *amount* of data received, but also to increase the *quality* of data collected.

Using wearables to monitor a study's patients away from the doctor's office allows clinical researchers a window into their day-to-day lives. It provides study teams a more complete, and therefore more accurate picture—gaining a more informed perspective which benefits the study's results overall.

Imagine how clear the picture of a patient's health would be without the guesswork? Clinical researchers no longer have to estimate how many hours of quality sleep a patient got or how many times they dreamt that night. They no longer have to estimate how long a patient's heart rate was elevated by exercise or for how long. They will know how many minutes a patient was active and even how wide their gait was while walking. This is not only fascinating, but it also provides clinical researchers with *real-world data and evidence that they can act on*.

The Future of Clinical Research?

The use of home computers, mobile devices (e.g., smartphones and tablets), wearables, and biosensors to gather and store large amounts of health-related data has been prominent for years. However, the COVID-19 pandemic and the challenges it exposed regarding the lack of access to proper healthcare put the adoption and implementation of wearables on the fast-track within the field.

The passive, secure collection of patient data holds the key to leveraging previously untapped potential, allowing clinical study teams to better design and conduct clinical trials and to answer questions previously thought impossible. In addition, with the development of new and sophisticated analytical capabilities, we are better able to analyze patient participant data points and apply the results of our analyses to meet the needs of each unique clinical study (e.g., medical product development and approval, etc.).

Partner with Companies That Can Handle the Logistics So You Can Focus on Patients

Are you getting the patient data you need when you need it? Are you keeping your studies on their timelines with no missed appointments?

No one knows better than you that your clinical study team's daily task lists are detailed and therefore time-consuming. Leveraging an in-depth, global network to ship and deliver wearables (and other devices) directly to your study's patients is a step in the right direction toward simpler, more efficient studies.

Once they receive the device, tech will already be integrated and ready to assist everyone involved. Its reminders will help automate many daily tasks, alleviating your study team's workload, but also increasing patient monitoring, compliance, and retention.

Companies that are boasting unique solutions for clinical research teams should also have the capability to gather clean datasets from patients, whether they are using one device or multiple wearables in a single trial. The more quality data we can safely and securely collect, the higher the chance of the study's overall success.

Significant Advantages to Adopting Technology

A User-Friendly Experience. Technology platforms that are customized to meet the needs of your specific study create uniform processes and send a message to participants that their time and participation is valued. Almost everyone in the world has now become accustomed to digital interactions in their personal and professional lives. They will expect the same level of digital ease and sophistication during their period of participation in a clinical trial.

Increased Patient Compliance. Protocol deviations in clinical studies lead to issues with compliance. In addition to the implications of increased cost, these deviations may result in unusable data and create avoidable delays within clinical trials. Implementing a technology platform dramatically reduces these risks.

Remote Access and Interactions. Decentralized, virtual, and hybrid clinical trials give participants the flexibility to participate in clinical research without the need to visit sites for every step and benchmark within a trial. Technology tools also allow patients, legal guardians, caretakers, etc. to read and sign forms at their own convenience, regardless of their location; as well as for all necessary digital signatures to be captured safely and securely—remotely—leading to better recruitment and retention rates at sites.

Seamless Workflows. Clinical site staff across the globe serve an ongoing flow of patients, often for multiple trials at a time. Technology tools and platforms ease their efforts and simplify the complex process of tracking consents and protocol amendments by generating timely alerts, reminding their patients to take action to complete the necessary tasks that are due.

Patient Recruitment and Diversity. Again, the usage of multimedia messaging allows clinical study teams the opportunity to recruit larger and more diverse groups of patient participants—remotely across the globe—serving traditionally underrepresented populations.

Concerns and Challenges Addressed

Clearly, we've demonstrated that there are many advantages to integrating a true end-to-end technology platform and solution into clinical trials. That said, there are also concerns regarding potential challenges that are associated with the implementation of technologies that we should address.

One question that always comes up relates to the costs of implementing technology solutions. In the short term, the costs associated with the customization and implementation of your study's workflows are higher than traditional models of execution. However, these costs should be considered as an investment in how you will conduct clinical trials moving forward, rather than just another cost with only short-term benefits. If patient recruitment increases, along with patient compliance and patient retention throughout the clinical trial, a site or sponsor has to consider the real impact on the overall bottom line—saving not only money but valuable time for the clinical study's staff, all of which increases efficiency and data integrity.

Concerns over data security and patients' privacy are also, of course, valid points when discussing the use of any web-based technology. Any clinical research technology platform you consider implementing should already be compliant with the Health Insurance Portability and Accountability Act in the U.S., the General Data Protection Regulation in the European Union, and 21 CFR Part 11 of the *Code of Federal Regulations* expectations from the U.S. Food and Drug Administration. Some companies have also begun implementing features like facial recognition to verify and confirm a patient's identity prior to allowing access to documents that include personal, sensitive information.

The Future is Now

As a pandemic surged, the clinical research industry was challenged to find solutions regarding how to safely continue conducting clinical studies in 2020. We have whole-heartedly accepted that challenge and moved forward faster than anyone expected. These technology tools, platforms and solutions are poised to be “a new norm” of clinical trials all over the world. Encouraging sites and sponsors to adopt available technology solutions today will cast a wider net for patient recruitment, including diverse patient populations, as well as improve patient compliance, boost patient retention, and optimize consent data management—all while providing patient participants with a high-quality, engaging experience from the outset of the trial. We know we are on the right track—we just need to keep safely moving forward.

Resources

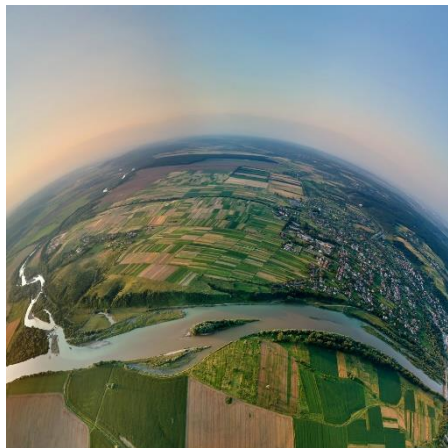
- Guidance: [Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products](#)
- Guidance: [Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products](#)
- Guidance: [Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products](#)
- Guidance: [Submitting Documents Utilizing Real-World Data and Real-World Evidence to FDA for Drugs and Biologics](#)
- Guidance: [Use of Electronic Health Records in Clinical Investigations](#)
- Guidance: [Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices](#)



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Unifying Clinical Data Flow to Improve Patient Outcomes

Jim Reilly



Over the past few years, managing clinical trial data has become more challenging as decentralized patient data sources grow and volumes reach terabyte levels. Instead of seeing clinical data management as a technical, back-office process separate from clinical operations, progressive leaders recognize its crucial role in improving trial efficiency to speed patient access to new and better therapies.

These leaders are developing innovative programs to integrate clinical operations and data management, driven by the need for a closer understanding of patient needs, especially in areas such as oncology. In 2020, for example, GSK set ambitious new goals for its clinical programs. The company has since exceeded those goals, reducing study builds that ranged from 12 to 21 weeks to eight weeks. GSK's [explanation](#) for its new benchmarks was simple: Every slowdown in study startup or lock times delays the availability of oncology treatments, negatively impacting patient lives.

Clinical leaders at Boehringer Ingelheim, the world's largest fully family-owned pharma company, also began to examine the gap between clinical needs and technology limitations much more closely to better serve patients. "Patients cannot wait to get innovative drugs," says Dr. Uli Broedl, MD, the company's senior vice president of global clinical development and operations, who discussed the history and goals of Boehringer Ingelheim's One Medicine initiative at Veeva Systems' recent R&D and Quality Summit.

The initiative aims to establish an end-to-end development platform that connects different operational and clinical data flows and automates processes. This will help Boehringer Ingelheim build a core technology engine to enable a unified, connected approach to clinical trials and product development.

Establishing a Strong Foundation for Change

Ultimately, technology is the key to improving clinical trial execution, Broedl says, but it requires a foundation based on process improvement and standardization. It also depends on having teams that approach their work with a patient-first mindset, possess the right skills, and are comfortable working at the intersection of clinical research and information technology (IT).

Change efforts at the company started with a transformative initiative called Medical Excellence, focused on developing the right employee mindset and consolidating and optimizing existing processes. Boehringer Ingelheim is also building a data lake to organize and centralize data, an effort that will eventually allow clinical data to improve decisions in areas such as quality and recruitment.

The company shifted from a "best of breed" IT system landscape to establishing a core technology engine to enable a unified, connected approach to clinical trials. This year, Boehringer Ingelheim launched One Medicine Platform, implementing cloud-based systems across clinical operations and data, regulatory, and quality management that are built on a single platform. Taking this approach will enable process automation by connecting data flows. "Once we have a good interface and uniform data layers, we can build bolt-ons to drive predictive analytics along the clinical development journey," Broedl says.

The Need for Connected Data

Change is essential to improving clinical trial efficiencies because today's clinical IT systems at Boehringer Ingelheim are complex, fragmented, and slow, forcing teams to focus on system maintenance and limiting their ability to bring added value to patients.

Broedl emphasizes the need to prioritize connectivity both within clinical and across functions.

Instead of various sources of truth due to multiple different systems, sponsors need one source across all systems. This approach will eliminate the scenarios playing out at many life science companies today, which include:

- multiple IT systems that cannot speak to each other without custom connections;
- complex workflows requiring expensive workaround solutions; and
- user interfaces that are difficult to work with and require end-users—especially at research sites—to log in and out of multiple systems daily.

Understanding Patients and Their Needs

Despite the industry's focus on patient centricity, clinical teams may still need to refine their perceptions of what patients need most. Instead of taking a transactional approach, in which performance is evaluated based on classical key performance indicators, teams should adopt a broader, patient-based perspective from the beginning when clinical programs and trials are being planned.

This approach will change their view of end-to-end customer engagement and lead to better results. Embracing connectivity across functions allows information flow and enables clinical teams to work together instead of in silos with separate data within electronic data capture products, clinical trial management systems, and trial master files.

Unifying Healthcare and Clinical Data

Broedl envisions a future where patient and site experience can be further improved as data from clinical and business platforms, such as for customer relationship management, come together. After all, he notes, healthcare professionals and clinical investigators “are the same people.”

Change on that scale will take time, but Boehringer Ingelheim’s business leaders are optimistic that One Medicine will improve clinical efficiency by unifying clinical data and operations to create a greater connection with research sites and patients. In the end, a focus on patients must drive these efforts and others like them in the industry. Success will be based not on incremental operating improvements, but on patient outcomes.



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FORM & FUNCTION

Development Velocity: Addressing Longstanding Challenges in Drug Development

Donna Conroy, MS



Throughout 2022, some of our industry's most influential leaders have expressed concerns about the economic and public health challenges that result from slow drug development. After fast-tracked COVID-19 therapies proved development can be accelerated, the status quo is being challenged.

It is time for our industry to address development's longstanding challenges—beginning with naming and defining the problem: *Development Velocity is the speed a pharmaceutical company moves a therapy through the development process and into the market.*

Development Velocity (DV) is a mission-critical metric that yields financial benefits and expedites time to market by enhancing both sides of pharma's ledger through cost reductions and earlier revenue. Incorporating DV into our industry's lexicon and best practices is vital to wholly accelerating drug development.

Defining Development Velocity

When a drug candidate emerges from discovery with great potential, the clock starts ticking on its trajectory toward commercialization. However, many variables impact how quickly—or how slowly—a therapy moves through development. This is its Development Velocity.

During the five-to-seven-year development process, pharma companies seeking U.S Food and Drug Administration approval must move a therapy from an Investigational New Drug application through the requisite phases of development to secure regulatory sign-off of a New Drug Application and then onto commercialization. While clinical trials are the most familiar element of the development process, the extraordinarily complex “business” side of development is equally vital.

The business side consists of 12 cross-functional teams (commercial, medical, health economics and outcomes research, regulatory, etc.) simultaneously conducting hundreds of interdependent tasks to bring a therapy to market. Commercialization is a milestone with high stakes; slow or impaired implementation of these cross-functional efforts can obstruct a company’s journey and drastically slow its DV—stalling or hindering time to market.

The lack of innovative technology solutions that focus on course correcting inefficiencies and redundancies in the development process is one of many factors that impacts the development journey. Teams rely on legacy processes that fail to take a holistic approach or that simply cannot scale to meet the complex needs of cross-functional teams. However, as technology advances and solutions are built specifically for the needs of pharma, the industry should now look to comprehensive technology solutions to achieve complex development goals.

What Impacts Pharma’s Development Velocity?

Efficiency and collaboration are chief among issues impacting a therapy’s development journey—either slowing down or speeding up the process.

Inefficiencies create bottlenecks that slow DV. For example, many teams rely on antiquated workflows (spreadsheets, countless meetings), manual analytical processes (data and outputs requiring aggregation), or costly vendor outsourcing to bring disparate clinical data and information together. As science drives decision-making, antiquated workflows open the door to slowdowns during complex pass-off points or due to incomplete or inconsistent knowledge transfer among teams.

The historic lack of pharma-first technologies is a key factor. To date, most technologies available to development teams consist of repurposed or retrofitted project management tools or siloed data analytics tools that fail to address the broader needs of cross-functional teams. Further, these manual processes, retrofitted technologies, and siloed point solutions result in a variety of outputs that require aggregating and stitching together, creating additional manual processes.

Corporate structure can also slow DV as the 12 cross-functional teams often work in siloes, each with different perspectives. Collaboration varies from team to team, and without a process roadmap in place, interdependent workflows lack cohesion. When these development challenges persist, the resulting loss of momentum extends timelines and escalates budgets.

Building development programs that lead to commercialization is a complex web to weave; doing so with speed and efficiency is another challenge. However, with the right tools, DV can be dramatically improved to accelerate a therapy's time to market.

Pharma's Mission-Critical Objective: Accelerate Development Velocity

As we saw with the expedited development of the COVID-19 vaccines, pharma is feeling increased pressure to bring life-saving and life-changing therapies to market faster. Yet as expenditures have increased, so has external pressure for pharma to lower drug prices.

Despite negative press surrounding profitability, pharma companies typically reinvest a large portion of net sales back into research and development (R&D) efforts. For example, among the world's top five pharma companies, 21% to 28% of net sales are [reinvested](#) back into R&D.

While profitability is important for the success of any corporation, pharma's additional driver for maintaining a healthy bottom line is to advance patient care. Strong return on investment (ROI) is needed for pharma to reinvest profits into additional R&D efforts. When profits shrink, R&D efforts may follow suit.

While our industry made tremendous strides in activating acceleration levers in its response to COVID-19, the frustrating reality is it still takes too long and costs too much to move a new

therapy through the development process. Costs have [nearly doubled](#) over the last decade. On average, companies spend [more than 10 years](#) and as much as [\\$2.8 billion](#) moving a drug candidate through the two-step R&D process of drug discovery and development. The time it takes to move a drug to commercialization impacts market exclusivity.

New therapies receive [20 years](#) of patent protection, much of which is used to safeguard the drug maker's rights before the therapy hits the market. Therefore, every day it takes a therapy to get to market reduces the window of market exclusivity and compounds cost pressure.

With development costs increasing and market exclusivity decreasing, ROI for new therapies is reduced, creating a concerning economic challenge for pharmaceutical leadership teams.

An obvious solution to this economic challenge is getting therapies to market faster with lower costs, precisely what accelerating DV aims to do.

The beauty of enhancing DV through technology is that it enables pharma to do well by doing good, to do more with less, to improve patient outcomes while simultaneously increasing top-line revenues and bottom-line profits. Therapies get to patients sooner and pharma can explore additional uses for existing therapies.

The path to accelerating drug development begins with a baseline measurement of a pharma company's current DV. Establishing this baseline is critical; without it, pharma cannot measure the impact of its efforts to improve DV—for as renowned business management theorist Peter Drucker famously said, “If you can't measure it, you can't improve it.”

Looking Ahead: Technologies That Accelerate Development Velocity

Segments of pharma have begun adopting R&D technologies to expedite both discovery of new molecules and clinical trials. Pharma companies that augment these investments with technologies that accelerate DV will be the big winners in the years ahead.

To do otherwise would be illogical: Why invest in artificial intelligence (AI) to discover new molecules if only to rely on the same old status quo, antiquated development processes to move those molecules toward commercialization?

By replacing manual processes with comprehensive AI-powered cloud platforms that support multidisciplinary efforts, development teams can easily scale to support enterprise-wide objectives.

Conclusion

As we usher in a new wave of technological innovation on the business side of development, new platforms are now available to meet specific needs and the complicated web of cross-functional teams. The market is ripe for advancements that address DV's role in pharma's current economic challenges so the industry can meet its goal of putting new therapies in the hands of the patients who need them most.

Improving Development Velocity creates faster and less expensive journeys to commercialization. Not only does speed to market enable better health outcomes because therapies get to patients sooner, but the lower costs allow pharma to reinvest in new or expanded therapies and continue balancing profitability while doing good.



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4 Big Data Trends Impacting the Future of Clinical Research for Natural Health and Wellness Products

Pelin Thorogood, MEng, MBA; Dr. Jeff Chen, MD, MBA



The convergence of four trends—some of which have accelerated since the pandemic—is transforming the clinical research industry. First and second, *virtualization* and *disintermediation* are changing access to research and the dissemination of its findings. Third, thanks to rapid growth in *digital health* and the *Internet of Medical Things*, we now have more data than ever about our health. Fourth, and perhaps most importantly, with the maturation of *big data*—

driven technology and artificial intelligence (AI), we can now make sense of these massive datasets to drive better decisions, whether on personal health, policies, and/or business. Here is a look at how each trend impacts the health and wellness industry.

Trend #1: Virtualization

As a trend which has been accelerated during the pandemic, virtualization democratizes participant access to trials. During the pandemic, researchers were forced to move clinical trials online, asking participants questions and sending products to their homes so they could self-dose. This was a rapid change from the traditional, physical trial, which was leveraging the existing infrastructure of universities, hospitals, and contract research organizations—and all the associated costs, including staff.

Virtualization allows companies of any size to conduct clinical research, due to the significantly reduced cost of clinical trials. It also brings diversity to where it really counts—to healthcare. Many groups have been traditionally left out of clinical trials, which have typically been focused on white males in metropolitan areas. Virtualization allows for women, different ethnic groups, and rural populations to be part of clinical trials. A poll taken in [2017 by Research!America](#) found that 30% of adults surveyed said they'd like to participate in clinical trials if they were more convenient and less time consuming.

With virtualization, we can open up access to all demographics, improving the heterogeneity of the sample population and therefore the generalizability of the research findings. Further, with sufficient numbers, each of these demographic variations starts becoming meaningful and begins to be representative of the population at large.

Large-scale and intentional heterogeneous studies enable inclusion of diverse ethnicities, genders, age groups, behavioral habits, and pre-existing health conditions, which in turn moves us closer to making personalized medicine a reality for more patients.

Trend #2: Disintermediation

In order to examine data from trials of pharmaceutical drugs, the U.S. Food and Drug Administration (FDA) needs tremendous amounts of infrastructure in terms of personnel, businesses, and other involved government agencies. That bureaucracy will not change anytime soon, since U.S. pharmaceutical companies are subject to FDA regulations and need explicit FDA approval before they can start selling their patented formulas.

However, a whole new world of health interventions is opening up, including exercise, functional foods, herbs, cannabis, meditation, breath work, acupuncture, or aromatherapy. These interventions don't need FDA approval or a doctor's prescription. They aren't so expensive that they need insurance coverage. They're already being sold today. They're democratized. They simply need access to fast, affordable clinical trials to demonstrate effectiveness to minimize risk of Federal Trade Commission action against false or misleading claims.

Virtualization and disintermediation eliminate the need for a mediator to share or communicate research findings. Typically, new medical research is published in esoteric medical journals that require paid subscriptions. It may take many years before healthcare professionals adopt that information into clinical practice and share it with their patients. In our opinion, such journals shouldn't be the gatekeepers of information, especially on interventions that can be acquired without a prescription. Data on the safety and effectiveness of nonprescription health interventions can—and we believe should—be disseminated directly to consumers. The explosion of digital channels to serve direct-to-consumer content in a variety of engaging formats offers an unprecedented opportunity to disseminate valuable data nearly instantaneously, instead of through a lengthy trickle-down effect. Imagine how many lives can be saved and impacted.

Trend #3: Digital Health and the Internet of Medical Things

The 21st Century CURES Act, passed under the Obama Administration, requires interoperability of healthcare data among payers, providers, and technology vendors. It also means patients can effortlessly share their data with whomever they choose, including researchers gathering large-scale data on the outcomes of health interventions.

Patients are now hyper-connected, and the Internet of Medical Things (IoMT) grants us access to levels and types of data that were previously uncaptured or untouchable by researchers. From smartphones and consumer wearables to medical-grade devices like wireless blood pressure cuffs, glucose meters, and electrocardiograms, we have the technology to capture data on how individuals are in their real, day-to-day lives, instead of from readings taken only in the hospital or clinic.

We also now have interoperability; when patients have easy access to their data across electronic health records, insurance claims, and laboratory results, they're empowered. They can use that information to switch to a new healthcare provider, or a new insurance carrier. Providers are also empowered to do things like switch to a new electronic health record system.

Trend #4: Big Data and AI

This last trend is especially exciting, as it perfectly builds on the first three trends in several ways:

- Through democratization of access for more formulations and a much higher diversity of participant population, enabled by virtualization and disintermediation.
- Through the vast quantity of high dimensionality of data on individuals, thanks to digital health and the IoMT.

We have access to an unprecedented and rapidly growing quantity of both retrospective and prospective data on more people than we've ever had in our history. Further, with the growing maturity of AI, we now have the opportunity to make good use of these data in many ways for better decision making.

We will experience a gradual shift in the coming years toward more trust and acceptance of AI and machine learning, new digital health capabilities, and more surveillance-type monitoring of patient populations. For example, the power of larger datasets and our ability to manage the holistic picture of our patients' data in the digital domain enable us to be far more predictive regarding individual health outcomes, based on demographic, behavioral, and preexisting conditions of patients. We can be far more proactive in how we diagnose and treat so that we can focus more on the root of human wellness, rather than simply reacting to symptoms.

The large datasets also give us the opportunity to not just research the questions we thought to ask, but to explore hidden correlations in the data to see how demographics, behaviors (e.g., coffee/alcohol intake), other prescription medications, and pre-existing conditions may play a role in the efficacy or side effects of the therapeutic studies.

These signals—even though they may not yet be conclusive—are the perfect hypothesis to drive further targeted research. The kind where we can anticipate patient health outcomes, explore hidden correlations for potential “signals,” accelerate and iterate research, enable precision targeting, and drive data-driven decision making.

A Future of Pharma *and* Farma

The future is both pharma *and* farma, not either/or. We're predicting a world of abundance where pharmaceuticals and plant medicines live side-by-side and support health and wellness for populations—with transparency on the safety and efficacy of pharma, as well as of ancient remedies.

We predict a future where we are using these products in combination not just to combat ailments, but to enhance human function, whether it's in terms of focus, creativity, physical strength, libido, or other desirable areas. We expect to see more affordable treatments offering better outcomes and fewer side effects to their target population.

We anticipate precision marketing with health and wellness products. Think digital marketing—but based on massive quantities of human health data. With this, AI-driven recommendation engines will match the right people with the products for their specific condition. We expect easily accessible clinical proof of effectiveness to empower consumers, healthcare professionals, and the entire supply chain in between.



Pelin Thorogood, MEng, MBA, is Co-Founder and Executive Chair of [Radicle Science](#), an AI-driven Proof-as-a-Service company offering the first easy path for non-pharmaceutical products to clinically prove their true effects beyond placebo by leveraging a crowdsourced, virtual, and direct-to-consumer approach, enabling research across diverse populations and conditions.

Dr. Jeff Chen, MD, MBA, is CEO and Co-Founder of Radicle Science.

PRESCRIPTIONS FOR BUSINESS

The Promise and Pressures of Biologics Research and Development

Christian Olsen



Biologic drugs have increasingly delivered treatments for cancer and rare diseases and continue to prove effective in other wide-ranging areas, from neurological and metabolic disorders to respiratory and cardiovascular diseases. However, along with the incredible potential biologics offer, there is also great pressure to discover and deliver novel treatments quickly and cost-effectively.

Background

Biologics represent a rising share of U.S. Food and Drug Administration (FDA) approvals with a market size projected to exceed [\\$700 billion](#) by 2030. According to The Antibody Society, more than 150 therapeutic monoclonal antibodies have been [approved](#) for use in the U.S. and Europe since appearing more than 20 years ago.

In 2018, RNA therapy first came on the scene with a drug that treats a genetic disease called hereditary TTR-mediated amyloidosis, caused by mutations in the transthyretin gene. Then Biogen discovered the wildly successful Spinraza (Nusinersen), which treats spinal muscular atrophy, a rare genetic disease that is fatal if untreated. Spinraza brought in almost \$1 billion in sales in its first year alone. Most recently it was an RNA-based vaccine that was developed to help fight the global pandemic.

The American Society of Gene and Cell Therapy (ASGCT) [reports](#) that, as of Q2 2022, 19 gene therapies, 18 RNA therapies, and 59 cell therapies have been approved for clinical use globally and many promising candidates are in clinical trials.

Investment in biologics research and development is strong, with ASGCT reporting that start-ups working in gene, cell, and RNA therapies raised nearly \$800 million in Q2 of 2022 alone. Interestingly, a trend toward financing and partnerships has emerged, letting investors and pharmaceutical companies support innovators through license agreements and partnerships without the full commitment of an acquisition.

Facing the Challenges

Even as the investments flow, biotechnology organizations face a conflicting reality. On one side, there is incredible potential. Biologics offers upsides like favorable safety profiles, longer patents, and relatively low generic competition compared to small molecule drugs. There is also rising demand for novel treatments for prevalent chronic diseases like diabetes and obesity, and biologics are poised to deliver; recent [examples](#) include work researchers are doing to:

- prevent the premature termination of protein expression caused by genetic mutation;
- inhibit or alter protein expression by modifying RNA, such as with enzymes or small molecule drugs;
- develop delivery systems for gene therapy and RNA drugs;
- apply protein degraders to conditions outside oncology;
- perform gene editing using CRISPR; and
- uncover potential targets and drug candidates using machine learning methods.

Unfortunately, the flipside to the potential is incredible pressure, as development costs for biologics are notoriously high. Further, the “clock” is ticking as patents approach expiration like Abbvie’s Humira (\$21 billion in 2021 sales alone), which expires in January 2023. Federal policies have also made “biosimilar” competition more viable.

In the realm of small molecule drugs, [generic](#) competition is well established and fairly straightforward. Manufacturing processes are standardized, and generics are essentially chemical equivalents to their originals, with only slight ingredient variation allowed. Generic small molecule drugs take advantage of abbreviated approval pathways and have markedly lower development costs compared to their reference products; they are often readily substitutable for their primary counterparts at the pharmacy and are priced around [80 to 85% less](#).

The playing field is different with biologics. Creating equivalents is just not as simple. Biologics are more complex—not only in their larger structures, but also in the complicated processes used to analyze, develop, and manufacture them. In fact, the term “generic” is not even used for biologics; instead, we have “biosimilars” or “biobetters,” which each have their own set of pros and cons.

Biobetters try to improve upon reference biologics, not just emulate them. They are currently considered new drugs and therefore receive patent exclusivity. While this means no fast-tracked approval process, it does mean developers can avoid waiting for the reference drug’s patent expiration, making it possible for a biobetter to beat a biosimilar to market.

Biobetters are subject to all the rigorous testing and trials required for a new drug. However, developers have a head-start, having a known target protein along with efficacy and safety data established for the reference structure. This knowledge can be used to explore things like structural changes, chemical modifications, or process alterations that could help deliver an alternative that is hopefully more efficacious, better tolerated, safer, easier to administer, or longer lasting than the original.

Further, while the call to lower drug prices and improve patient accessibility to novel biologic treatments is louder than ever, in the pursuit of biosimilars and biobetters, it all comes down to the data. Researchers not only leverage heaps of data related to a reference biologic, they also need to take into account its relation to the volumes of other data streaming in from their study of new candidates’ pharmacokinetics, pharmacodynamics, safety, purity, potency, immunogenicity, and response.

Conclusion

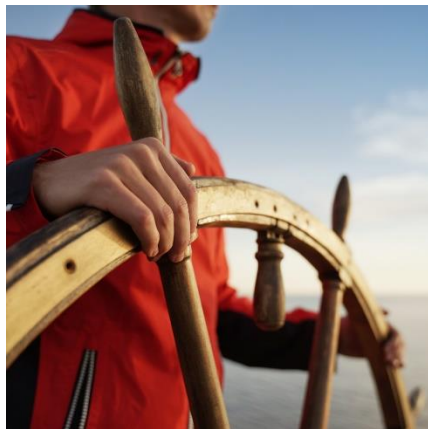
Some of the biggest hurdles for innovation are siloed data, fragmented workflows, and clumsy business practices. Those are coupled with the fact that biology is complicated. As the need for biologic drugs increases, innovators are left with no choice but to find new ways that help them work smarter and faster, starting in the earliest days of discovery. If we want to realize the full promise of biologics, we'll first need to tackle these challenges to reap the benefits.

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ON THE JOB

A Clinical Research Career Could be Your Best Path to Follow in Medicine

Talia Nikolao Hight, MBA



Pursuing a career in clinical research is undeniably a noble quest. Clinical research professionals are instrumental in safely bringing medications and therapies to market that improve and save the lives of millions.

Traditionally, however, going to nursing school or medical school was considered a necessary pathway to the ultimate goal of a long-term career in advancing medicine and contributing to the welfare of patients through research.

While this continues to be the case for many of those professionals who wish to be investigators on clinical trials, it has meant that, until recently, aspirations toward significant and sustainable participation in clinical research were limited for those seeking less-medically driven research team roles. Further, and all too frequently, the motivation that drove them to choose research—working with patients—would be overshadowed by the lack of resources at, and/or expectations of holding advanced degrees to work for, clinical research sites.

In any role, work at these sites has historically meant being consistently frustrated, flustered, overworked, and under-resourced. Research sites have traditionally lacked funding, staffing, or in some cases, even the most basic information technology infrastructure. Research coordinators to this day may spend inordinate amounts of time bogged down in hours of administrative work, managing heavy paperwork flows, and stuffing 1970s-era binders. Career path options for many people who wanted to work with patients were often limited to working at small, mom-and-pop research shops using archaic approaches.

In order to work in better resourced settings, the alternative choice was too often presented as enlisting with a monolithic, slow-moving organization, such as a major pharma sponsor, contract research organization, or academic medical center with little opportunity for direct patient impact and slower career advancement.

Fortunately, the outlook for anyone enticed by the prospect of clinical research and the role it can play in advancing medicine is much brighter today. Anyone intrigued by the possibilities can pursue a potentially prosperous career complete with advancement opportunities and joy for one's work. The clinical research career forecast is brightening for a variety of primary reasons explained in the following sections.

More Dollars to Sites and People Doing the Work

Government organizations and pharmaceutical sponsors have long allocated big dollars toward clinical trials. Little, however, was allocated toward building and developing tools that would allow researchers to do their jobs more efficiently and happily.

The pandemic underscored the critical need for clinical trials to be executed quickly and with precision. Pharma finally seemed to recognize that, for more trials to be successful like those developed to combat COVID-19, more money and resources need to be invested and directed toward the people doing the work at the research site and in the community. The renewed focus on arming sites with needed resources makes it more possible for a wider range of practicing physicians to engage in research. These improvements augment the research staff's experience, creating more satisfaction and joy with every member of the research team.

A Debt-Free Career in Medicine and Patient Care

Careers in clinical research were once the province of students who had made the decision to pursue medicine in their formative years and set out on the requisite educational path. Today, the picture is different—clinical research is available to anyone, no matter how many organic chemistry and biology classes they took in college, even if the number is zero. A pre-med focus is not necessary, and prospective researchers can have any college degree.

Companies are training, teaching, and investing in the professional development of prospective researchers who can join the field without advanced degrees and certifications, though these can and, in some cases should, be pursued down the road—ideally with financial support from the employer. No longer saddled with having to know everything about conducting trials from the moment they are hired, coordinators can focus on and pursue expertise in specific areas of interest. Perhaps most appealingly, clinical research offers a pathway to medicine and patient care without incurring backbreaking medical school debt.

Modernization and Digitization Are Finally Catching Up

Any industry seeking to attract the best and the brightest as they enter the workforce must provide access to modern technology that will reduce manual and administrative tasks and allow for greater time and focus on high-impact work. After years of remaining far behind the technological curve, the clinical research industry is finally making the necessary investments in modernization and digitization, driven in large part by the aforementioned increase in pharma investment. Additionally, where vendors and service providers once developed solutions primarily for deep-pocketed pharma sponsors, new suites of tools and solutions have emerged to help study coordinators and research investigators do their jobs more efficiently and enjoyably.

Conclusion

In the final analysis, the perceptions some have of a career in clinical research leading to an overworked, underappreciated, paper-pushing dead end are being reversed. Clinical trial sites, study coordinators, and investigators in the community are receiving the technology and resources needed to modernize the important work that they do. Clinical research now offers a more approachable, high-paying, and prestigious career path to anyone seeking to positively impact medicine and the people it benefits.



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OVER THE TRANSOM

Navigating the Data Stream: We Will All Meet Together in the End

Edited by Gary W. Cramer (gcramer@acrpnet.org), Managing Editor for ACRP



The arrival of December each year has a way of trying to make me think big thoughts while stuck at home waiting for kayaking weather to return. Certainly, 2022 (no less than the previous few years) has given us all a lot of large—and sometimes seemingly intractable—challenges to ponder upon and then take our best cracks at overcoming. More and more, it seems to this old school editor that while it's the digital-, data-, and technology-driven “solutions” to what ails different wings of the clinical research enterprise that are gaining

the most attention these days, there is still much to be said for the virtues of more practical methods for tackling certain kinds of troubles. I suppose that my big thought, if I really have one worth sharing here and am not just mumbling into my own beard, is that one must have the wisdom to know the difference between a scenario that calls for one approach versus the other.

Here are some examples of how folks in the real world are thinking about and confronting some big challenges in clinical research with a little bit of help from column A and a little bit from column B (no endorsements implied). It is my hope that whichever approach we have to making our way down the stream toward our solutions, in the words of a certain spiritual viewpoint, we will all meet together in the end.

What's Next in 2023 Health Trends

Syneos Health® [has released](#) its *2023 Health Trends: Personally, Purposely Building What's Next*, and cautions that with artificial intelligence (AI) and machine learning producing an era of rapid new pathways, plus an industry-wide push for equitable representation in clinical trials, 2023 will be a catalytic year for biopharma clinical development and commercialization.

The report predicts that technological evolution will likely lead to profound changes in how organizations think about and learn from data. Syneos Health expects AI and machine learning will help drive strategic decisions to accelerate the commercialization of new therapies to patients. Simultaneously, as the healthcare environment grows in complexity—with increasing regulatory scrutiny and new technologies—the urgent need to bridge the gaps between data, medical information exchange, and strategy will drive demand for Medical Affairs innovation.

According to Leigh Householder, executive vice president and managing director of Technology and Data Solutions, Syneos Health, “[W]e expect 2023 to be the year AI moves from promise to performance, helping organizations realize the value and impact of our understanding of population health, improving global data, refining clinical trials, and helping with the development of new vaccines and cures.”

The report highlights 12 trends set to catalyze the year ahead align around the themes of Technology Evolution, Human Engagement, and Healthcare Advancement.

Improving Self-Administration of Injectable Drugs in Clinical Trials

The future of clinical trials is becoming more reliant on connected medical devices for collecting data at the point of care, reducing the need for costly patient visits and cumbersome manual data acquisition. Therefore, Haselmeier, a medmix Brand, and AARDEX Group [have joined forces](#) to tackle the challenge of managing patient adherence during clinical trials.

Haselmeier has developed a wireless connected drug delivery solution that can be integrated into AARDEX Group’s adherence software. They say that the combination of the two systems allows researchers to understand and manage patient adherence in clinical trials testing self-injection

therapies. The D-Flex injection pen is at the heart of this connected solution. It allows for simplified adaption of specific injection dose volumes by changing only one component. This saves time and cost during clinical testing, especially with dose-ranging studies, because the same pen can be used for both clinical testing and product launch, eliminating the need for additional equivalence and human factor studies and reducing time to market.

The overall D-Flex Logbook consists of the disposable D-Flex injection pen and a connected cap, which replaces the standard cap of the pen. This set-up does not impact patient behavior and results in no additional training. The connected cap tracks injection dose, temperature, and time of up to 1,000 injection events. It can securely transfer data in real-time to AARDEX's MEMS Connect or any other pre-existing data management system via Bluetooth Low Energy.

Educating Dermatologists and Nephrologists on Racial Disparities in Lupus Trials

The American College of Rheumatology (ACR) [has released](#) Continuing Medical Education (CME) for dermatologists and nephrologists to help them learn more about clinical trials for lupus patients in their respective treatment areas and the importance of getting more of their African American/Black patients enrolled. The new CME is part of the ACR's "[Materials to Increase Minority Involvement in Clinical Trials](#)" initiative to provide nephrologists and dermatologists with specific information on racial disparities in lupus clinical trials, why it's important to increase minority participation in them, and the barriers providers face when encouraging patients to participate.

"Skin and kidney symptoms are common in lupus patients and there are clinical trials specifically targeting these two organ systems. The CME training addresses barriers like patient mistrust, lack of familiarity with trials, and an intimidating consent process," said Rosalind Ramsey-Goldman, MD, DrPH, chair of the ACR's Collaborative Initiatives Committee. "It also addresses facilitators like culturally sensitive communication and social support by emphasizing skills that provide support for both the provider and the patient."

More information about the ACR's work on lupus awareness and educational programs can be found at www.thelupusinitiative.org.

How Do You Measure Success in Autism Clinical Trials?

How do you know if a treatment for autism is effective? That's a question that has no easy answer—due in large part to the heterogeneous nature of autism spectrum disorder.

“There's so much variability in how these children present, what their needs are, what treatments might work, and how they change over time,” says Shafali Spurling Jeste, MD, chief of neurology and co-director of the Neurological Institute and Las Madrinan Chair at Children's Hospital Los Angeles. “So how do you know if a drug or treatment is working? It's not straightforward. We need more objective measures.”

Finding and validating those measures is the goal of the Autism Biomarkers Consortium for Clinical Trials (ABC-CT), one of the largest autism research projects in the country. Jeste is the principal investigator for the study at Children's Hospital Los Angeles, one of five centers participating in the National Institutes of Health–funded study, which is based at Yale University and includes Boston Children's Hospital, Seattle Children's Hospital, and Duke University.

[According to Jeste](#), the challenge is that researchers may have a good therapeutic, but they can't measure its success without the right biomarker or patient selection tool, or they may be measuring the wrong endpoints. Researchers need to develop a better infrastructure for clinical trial readiness, and that's what ABC-CT is trying to create by gathering large-scale data from across the country to validate measures for use in future clinical trials.



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