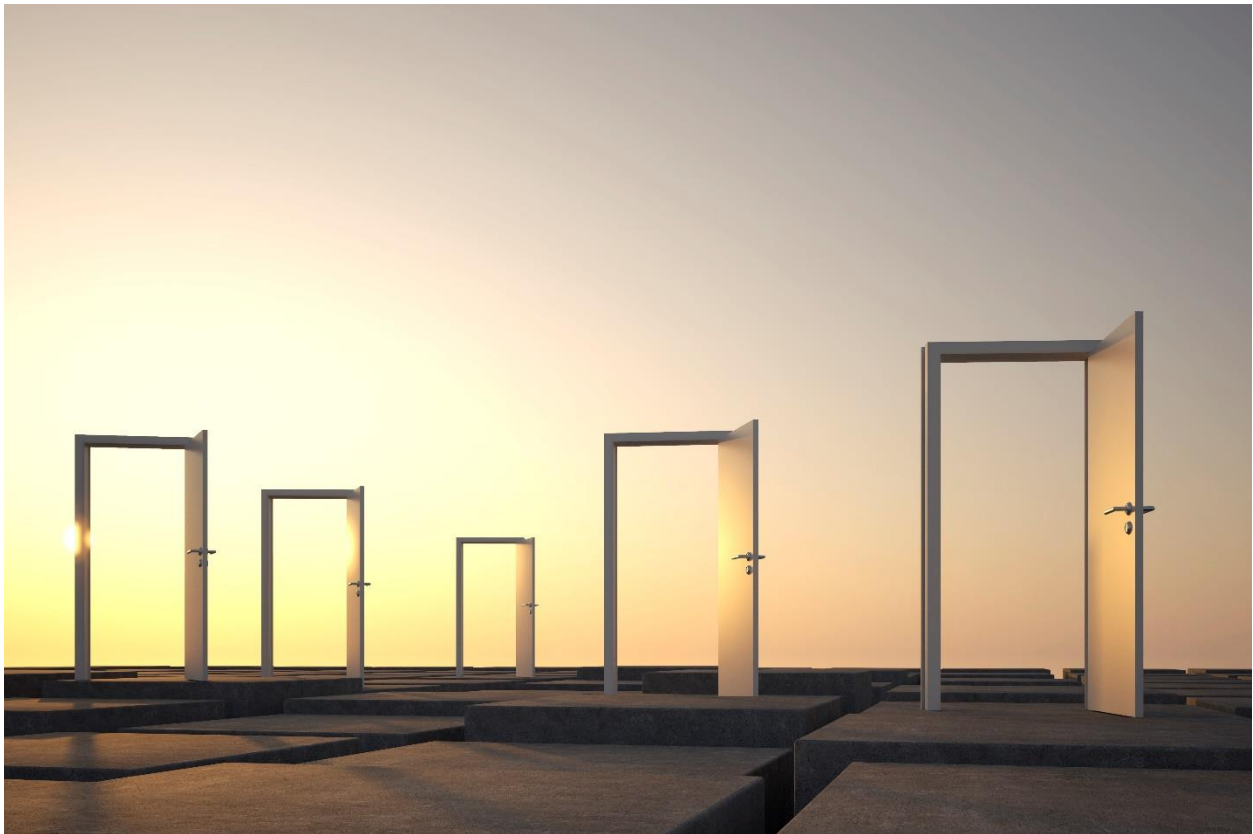


Clinical Researcher

The Authority in Ethical, Responsible Clinical Research

July 2021 (Volume 35, Issue 5)



Informed Consent: Opening New Doors on a Protean Process

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EXECUTIVE DIRECTOR'S MESSAGE

Why I'm Here

Susan P. Landis

[*Editor's Note:* With the retirement of former ACRP Executive Director Jim Kremidas in May, this is Susan's first message for *Clinical Researcher* since she took over the role in June.]



Last year, just as we began to deal with COVID-19 as a nation, my husband felt something in his chest. What started as a case of “Dad has COVID” ended with the discovery of a 95% blocked coronary artery and the rush into life-saving stent surgery. Blame it on genetics. At the time, there was nothing more my husband could have been doing than he already was with his diet and exercise to lower his bad cholesterol and raise his good.

Enter statins and, more recently (for him and other cardiovascular patients), a PCKS9 inhibitor that can dramatically lower bad cholesterol. To every clinical research professional who helped to bring these new therapies to market, my thanks is truly *heartfelt*.

A Crash Course in the Enterprise

I didn't know much about clinical research when I joined Quintiles (now IQVIA) more than a decade ago. My background was in marketing and communications for technology, data, and telecommunications companies. At Quintiles, I partnered with executives in every area of the company—clinical operations dealing with the “bench” research and development of potential drug products and the “bedside” development of the most promising candidates through clinical trials and studies; commercial operations supporting the marketing of approved, branded drugs; consulting services exposing me to comparative effectiveness research and formularies; outcomes research demonstrating the importance of real-world evidence in determining effectiveness and formulating corporate strategy. It was a front row seat to the workings of a global contract research organization and a crash course in how the larger clinical research enterprise functions.

An Academic Perspective

When I later joined the Duke Clinical Research Institute, I experienced the complexities of large government grant-funded studies and coordinating centers, and the amazing teams needed to support the most important and interesting clinical research being done across many therapeutic areas. I was part of the work at Duke and other academic institutions to usher in new ways to conduct clinical research—involving pragmatic clinical trials, patient-reported outcomes, master protocols, and virtual trials to name just a few. The group I led supported trials directly, particularly around patient engagement, digital health, and direct-to-participant studies.

Clinical research is an enterprise based on ideas. It's the engine for every new therapy brought to market and prescribed to those in need, and the foundation for critical protections and improvements in public health. In the United States, this may never have been as clear as it is today to a public that has lived through a pandemic. Equally, clinical research is an enterprise that cannot bring about that progress without *you*—the dedicated professionals who contribute your time, talents, and energies to improving health outcomes for all. We could not do it without you; thank you.

The New View

That's why I'm here. In my career, I've had clients and customers. Now I serve you, the members and stakeholders of ACRP, along with the Association's talented staff and volunteers as we collaborate to deliver timely educational programs, engaging content, and an exciting annual conference in person again next year. Importantly, I want us all to have a hand in shaping clinical research through initiatives that address diversity, equity, and inclusion, which in the end will serve to improve the conduct and outcomes of your work for the betterment of public health.

Thank you for this remarkable opportunity. Thank you for being here, too.

Susan P. Landis (susan.landis@acrpnet.org) is Executive Director of ACRP.

CHAIR'S MESSAGE

Thirty, Sixty, Ninety Days

Erika Stevens, MA



What does ACRP expect of our new Executive Director?

As a seasoned leader, Susan Landis hit the ground running on June 14 to learn about ACRP's members, certifications, educational programs, and initiatives.

Developing a deep understanding of ACRP requires listening, evaluation, planning, and execution. Conducting a SWOT analysis (strengths, weaknesses, opportunities, and threats) of the Association provides valuable insight into the existing capabilities and opportunities for the future.

The initial ask of Susan includes such an assessment, focused on sustainability, growth, and development for ACRP. In the first 30 days, key skills include listening to and learning from the Association Board of Trustees and the Academy Board of Trustees, and ACRP's staff, committees, key stakeholders, and members. After the initial look at "everything ACRP," with perceptions and opportunities revealed, collaboration will drive ideas.

Next up within the first 60 days is leveraging existing key organizational objectives in terms of strategic development and alignment. Finally, by the end of the first 90 days, we should begin seeing a reinvigoration of engagement from our members that will drive the Association's plan forward.

Where will ACRP be next year? Or in 2026 or 2031? However many years down the road we go, the focus will be on the members we serve, because in clinical research the people are everything.

I wish you all the best jusqu'a la prochaine fois (until the next time),

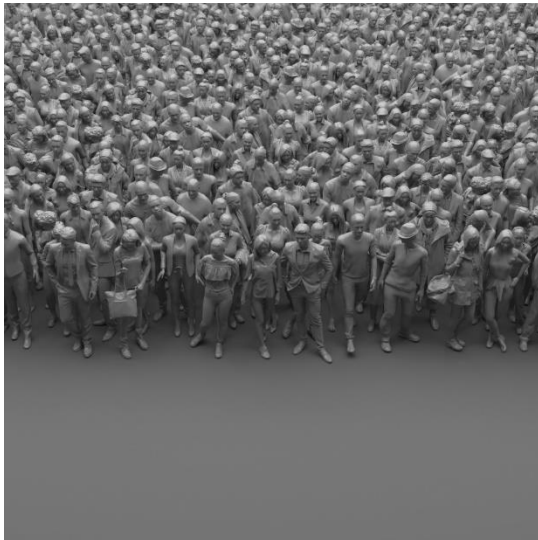
A handwritten signature in cursive script, appearing to read "Erika Stevens".

Erika Stevens, MA, is the 2021 Chair of the Association Board of Trustees for ACRP.

SPECIAL FEATURE

Consent Process Best Practices for Special Populations to Reduce Perceived Pressure to Participate in Clinical Trials

Sean Horkheimer, JD, CIP



When recruiting participants for a clinical trial, the U.S. Department of Health and Human Services (HHS) regulations require that “An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence” (see 45 CFR 46.116 in the [Code of Federal Regulations](#)). Coercion occurs when there is an explicit or implied threat of harm

used to obtain compliance. Undue influence occurs when an offer of an excessive reward or other benefit is used to obtain compliance.

Whether a potential clinical trial participant is vulnerable to coercion and/or undue influence is often situational. A potential participant may be vulnerable in one situation but not in another; this will depend on the context of the participant’s involvement and the relationship between the participant and the study team. For example: college students may be vulnerable when recruited for research conducted by their professors due to the power imbalance between the parties, but would not be considered vulnerable when recruited for research that is unrelated to their education or status as a student.

Coercion and undue influence can result in a situation where a potential participant feels pressured to enroll in a clinical study. This perceived pressure undermines a potential participant's autonomy and ability to provide meaningful informed consent. Some participant populations are more susceptible to this pressure based on their unique circumstances—prisoners, military personnel, elderly patients in residential healthcare settings, and students can all face additional pressure to participate when asked to enroll in research.

In the case of prisoners and military personnel, the regulations directly address this situation by imposing additional requirements for study teams and institutional review boards (IRBs). In the other cases, the consent process can be designed to minimize the participant's perceived pressure to enroll.

Let us examine the regulatory requirements and consenting best practices for these participant populations.

Prisoners

Prisoners are involuntarily confined or detained individuals in a penal institution (45 CFR 46.303(c)). Compared to non-prisoners, they have very little control over their daily activities. Prisoners are also subject to punishment by correctional officers for any misconduct or violation of strict prison rules. In this precarious situation, they have greatly reduced autonomy and are vulnerable to coercion and undue influence.

Subpart C of the [Common Rule](#) (Federal Policy for the Protection of Human Subjects) enacts additional regulatory protections for participants who are prisoners (45 CFR 46.301 et seq.). IRBs can only approve research that falls into specifically delineated categories (45 CFR 46.306(2)). To prevent undue influence, enrollment should not provide the participant with advantages in terms of living conditions, medical care, quality of food, amenities, and opportunities for earnings compared to the regular prison population that are of such a magnitude they undermine the potential participant's ability to effectively evaluate the risks of the research (45 CFR 46.305(a)(2)). To prevent coercion, the consent process should inform potential participants that their involvement will have no impact on decisions made concerning their possible parole (45 CFR 46.306(a)(6)).

Aside from these regulatory requirements, there are some consent process best practices that can reduce a prisoner's perceived pressure to participate. Members of the study team should identify themselves and their relationship to the prison at the start of the consenting process. If the study team includes members who are employees of the prison system, they should consider whether the person obtaining consent should be someone independent.

The warden and any prison administrators who have the ability to punish or reward participants should not be present during the consenting process, if possible. Their presence could be perceived as a subtle form of intimidation or possible promise of better treatment that will impact a potential participant's decision to enroll in the research.

The consent form should outline the extent to which prison officials will be able to access and review the research records. Participants will be interested to know if they will be identified individually or if results will be collected and stored in aggregate form. If the research is designed to examine prohibited activities taking place in the prison system and participant anonymity is essential to protect the participant's rights and welfare, the consent process for each individual participant should take place in private, outside the view of other inmates or correctional officers (this may also extend to the research activities, if necessary to protect participant privacy).

Military Personnel

In many ways, military service is defined by rigid hierarchies, deference to authority, and the expectation that all orders from the chain of command are followed. As such, military personnel can feel additional pressure to participate in research when it is presented to them in the context of their service.

Federally funded research recruiting military personnel is governed by the Department of Defense (DoD) regulations (32 CFR 219.101, DoD's adoption of the Common Rule). Additionally, DoD Instruction (DoDI) 3216.02 outlines additional requirements and guidance for research conducted involving DoD-affiliated personnel. This instruction document defines DoD-affiliated personnel as service members, reserve service members, National Guard members, DoD civilians, and DoD contractors.

Per DoDI 3216.02(3.9)(f)(3), military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to enroll in human participant research. Subsection (4) requires these individuals not be present during recruitment sessions or the consent process. If potential participants are approached in a group setting, this means their superior officers should not be present.

For minimal risk research, an alternative consent process may be appropriate. For example, in a survey study for which results are aggregated and linking to individual participants is not required for data analysis, informed consent could be obtained from the participant via an electronic platform during a time when he or she is not on duty. If necessary, participants can contact members of the study team with any questions they have before consenting.

For more than minimal risk research where recruitment is conducted in a group setting, the DoDI outlines additional protections. The IRB must appoint an independent ombudsperson to supervise the recruitment activity and consenting process. This person should explain to participants that their involvement is voluntary. They should also ensure the IRB-approved recruitment script, digital materials, and consenting process are followed (DoDI 3216.02(3.9)(f)(6)(b)).

Members of the study team should identify themselves and their relationship to the DoD as part of the recruitment and consenting process. Participants should be informed of the extent to which the research records may be accessible by the military. If the research is covered by a Certificate of Confidentiality, the consent form should explain the scope of this protection along with any exceptions that may limit it.

Compensation of DoD-affiliated personnel while on duty is prohibited, with some limited exceptions defined by statute (DoDI 3216.02(3.9)(f)(7)). As such, study team members should be aware of what they can and cannot offer as compensation to these participants.

Elderly Patients in Group Healthcare Settings

The biggest area of concern for elderly participants who reside in a residential healthcare facility is their decisional capacity or ability to consent for themselves. Elderly patients may have reduced mental capacity that is temporary, progressive, or permanent due to any of the

following: ongoing disease processes, acute urinary tract infections, neurological disorders like stroke or dementia, psychoactive medications, head trauma, or even past substance abuse. This means evaluation of an elderly patient's mental capacity is an essential step in any consenting process and should be an ongoing consideration throughout the duration of a research study.

The regulations do not direct specific requirements for consenting participants with reduced mental capacity, but they do identify individuals with impaired decision-making capacity as likely to be vulnerable to coercion or undue influence (45 CFR 46.111(b)). As such, the study design should incorporate additional protections for these participants. The research procedures should involve regularly assessing the participant's capacity throughout the study and obtaining consent with the help of the participant's legally authorized representative (LAR).

Even if the planned research is short in duration and a potential participant is otherwise decisional, it is advisable to involve an LAR or family member in the process. An otherwise alert and decisional elderly patient may not feel comfortable asking questions or voicing his or her objections in this setting. The participant's LAR or family member can serve as an advocate during the consenting process to voice any concerns or objections, if needed.

For research that presents more than minimal risk, the study team should plan for a longer consent process by conducting the discussion over multiple visits. This will provide the potential participant and his or her LAR with a chance to review the consent form in detail and formulate any questions they may have for the study team. This will also let the elderly patient discuss participation with the LAR privately. Because patients have an ongoing relationship with the care facility where they stay, they may be reluctant to refuse to participate for fear of upsetting their caregivers or the study team members who may also be providing them with clinical care. Extending the consent process to give the patient and LAR time to discuss their concerns reduces this feeling of pressure to participate.

For longitudinal studies that follow the progression of disease resulting in reduced capacity, it is advisable to have the participant's LAR identified ahead of time even if he or she is not needed during the initial consenting. This is especially important if the disease progresses and the formerly decisional participant is no longer able to adequately evaluate his or her own needs and

interests. Some progressive conditions have good days and bad days, and a participant's capacity may vary along a spectrum. An LAR who is familiar with the participant's personality and medical history will be able to step in for the participant to evaluate continued participation when necessary.

Students

Although students are not granted additional protections by the regulations, [they can still be considered vulnerable](#) by virtue of their concern for their own academic well-being and the power differential between them and the study team working with their professor. As such, study team members should adopt the following best practices to reduce the pressure to enroll that these potential participants may feel.

The study team should not include the student's professor as a member, since potential participants may be concerned that they will receive a bad grade or other punishment if they do not agree to enroll in the research. If this situation cannot be avoided, the study team should arrange to have someone other than the professor obtain consent from participants. Ideally, the professor should not be present during the recruitment and consenting activities.

If possible, the study team should design the protocol in such a way that the professor will not know who participates and who does not. For example, recruitment for research involving an anonymous survey could take place in person, but the study team could request a waiver of documentation of consent so participants will not have to provide their names on forms linking them to their participation.

For research that offers extra credit as compensation for participation, the study team should arrange to have an alternative option available to students who do not wish to participate, as some students may feel pressured to enroll in research that they would otherwise avoid to obtain the extra credit they need to get a good grade. This alternative option should involve a similar time commitment and level of effort—for example, a research survey that takes an hour to complete could be presented alongside an assignment that takes about the same amount of time.

Ideally, there should be protections in place to anonymize which students participated in the research and which students opted to complete the extra credit assignment instead. These protections should be clearly communicated to the potential participants as part of the consent process.

In addition to perceived pressure from the study team, students may also experience peer pressure to enroll (or not enroll), depending on their age. If this is a concern, study team members should conduct the consent process privately rather than in a group setting. Team members could also consider asking the students to not discuss their participation with each other until after the research activities are completed.

Conclusion

When conducting research in participant populations that are more susceptible to feeling pressure to participate, study teams need to be mindful of regulatory requirements and adopt a consent process that minimizes this pressure. Depending on the circumstances, this may require additional consent disclosures, identifying different individuals to conduct recruitment and obtain consent, changing the consenting setting, relying on the participation of an LAR, or designing the research procedures to limit who on the study team knows who participated. A well-developed consenting process will reduce a participant's perceived pressure to enroll in the study.



Sean Horkheimer, JD, CIP, is Regulatory Chair at WCG IRB, which conducts ethical reviews of clinical research protocols and studies and has more than 200 members on boards accredited by the Association for the Accreditation of Human Research Protection Programs, Inc.

SPECIAL INTERVIEW

The Vital and Ongoing Process of Modernizing Informed Consent

Gary W. Cramer with Alison Holland and Pamela Tenaerts, MD, MBA



In this special interview with thought leaders on clinical research processes from Medable, we concentrate on how clinical trials team members and technology trends are catching up to each other in the pursuit of increased efficiencies in the conduct of informed consent.

Q: Consenting participants across multiple study sites, potentially in multiple countries, is no easy process if sites are using different technology tools or some have electronic informed consent (eConsent) and others are still using paper-based processes. Are major sponsors and sites anywhere near the day when a common, high-tech eConsent tool will be in use in most cases?

A: As voices on inclusivity in clinical trials have become louder, it has never been more important to provide effective support for the informed consent process consistently across multiple locations. Certainly, the pandemic made eConsent a necessity, but even as onsite consenting resumes, technology adoption continues to grow as it helps reduce travel requirements and aids in comprehension and knowledge-sharing to augment the direct physician-to-patient meeting.



Utilizing a flexible eConsent module on a platform that offers other trial technologies, such as televisit and electronic clinical outcome assessment capabilities, reduces site burden when considering the overall trial requirements. Further, an eConsent tool that supports a country- and site-specific approach with workflows for multiple signatories, remote and onsite processes, and digital and print-to-sign capabilities, will ensure that an

advanced tool can be applied across a study, or portfolio of studies, offering consistency, standardization, and technology familiarity at the site level.

—Alison Holland, Executive General Manager of Decentralized Trials for Medable

Q: Reconsenting of participants due to changes in the study protocol is seen as a necessary, but tedious, practice. How can a more high-tech version of informed consent help?

A: Consent is an ongoing process, often further necessitated by protocol amendments and/or study data updates. With advanced eConsent technology, trial teams have access to consent templates, can create new versions, archive old versions, and change consent language on demand while following the necessary approval steps. It's critical to ensure participants are always consenting on the right version, and a digital format makes this much easier as electronic workflows are continuously able to be updated. Most eConsent systems also incorporate active version management and are trackable, which dramatically reduces the burden on sites. They offer real-time monitoring of consenting and reconsenting updates, with notifications and reminders plus archiving and audit trail features, ensuring that re-consenting is streamlined for both participants and sites. —Holland

Q: What about cases in which the same consent details need to be presented in multiple languages depending on the site locations? Is eConsent technology making the language barrier any easier to handle for research teams?



A: Effective and compliant consenting is underpinned by the need for participant comprehension and knowledge transfer. This remains a critical part of the eConsenting process, making it crucial for solutions to support the local language options approved for use with the anticipated participants. Part of the consenting process can involve direct communication with the participant by the clinical study team, but it can also be done remotely. In addition, eConsent solutions should follow human-

centered design principles to provide patients with an intuitive experience and increased modality flexibility. This may include the opportunity to deploy local language multimedia

options such as videos. All information, documents, and multimedia must be available for review at any time by participants in their local language.

Multi-language capability in eConsent solutions helps overcome language barriers, as does data localization. Specifically, local cloud data residency supports this on the back end using a poly-nimbus cloud structure to comply with local regulations while making data available to those who need it in their language. Modern eConsent technology incorporates country- and site-specific configurations in local languages and reflects local cultures. Solutions should also provide 24x7 local language support and consider concierge services to enhance the participant experience.

—*Dr. Pamela Tenaerts, Chief Scientific Officer for Medable*

Q: What do we know from experience about how the ease or difficulty of an informed consent’s terminology and the process itself affects potential participants’ likelihood of signing on for a study?

A: Advarra’s recent “[Retention in Clinical Trials](#)” survey found that there may be an opportunity to improve patient retention if the consenting process is improved. The study found that 35% of patients who dropped out early cited difficulties understanding the informed consent form. However, eConsent systems that offer the opportunity to use alternative methods to communicate information to the patient, such as videos, audio, or interactive “knowledge checks,” increase comprehension during the consenting process.

At Medable, we are currently deploying more than 45 studies globally that use our eConsent module, generating new evidence around uptake. We are already seeing a dramatic increase in engagement with patients who say they are excited to have more options that allow them to explore entry into a clinical trial from a non-hospital or clinic setting. Being able to dig through all that content in the consent form at their own pace and wherever convenient sets patients up for a much better experience and enhances their engagement with their clinicians/study team. It makes clinical trials more interesting and accessible to patients around the world. —*Holland*

Q: How does one go about scientifically proving or disproving the effectiveness of one way of conducting informed consent vs. another?

A: This is a great question, and something that came up multiple times by viewers of a recent [Medable webinar](#). The truth is, the technology has not been in use long enough across enough different types of studies for there to be a simple answer. To level set, we do not have data on how well the current informed consent process works in a paper environment either, so there is no baseline for comparison. According to a [McKinsey](#) study, 62% of clinical trial investigators in the U.S. and 76% in investigators in the U.K. expect e-consent adoption to increase post-pandemic—one potential indicator that consenting through digital mechanisms is beneficial. It is intended to improve the process, increase comprehension, impart greater consistency across trials, remove many time-consuming manual processes, and improve the patient experience.

One of my areas of focus at Medable is to generate evidence on eConsent using specific performance metrics to prove its value. For example, time and date stamps allow us to measure speed and efficiency. Comprehension checks allow us to capture patient feedback around understanding throughout. Further, videos can aid comprehension. We can also use workflow management tools to prevent people from bypassing certain parts or fast-tracking through the informed consent form without reading and understanding everything they are consenting to in the document—another measurement. Again, there is no baseline to measure against, so we need to start on a macro level—for example, are the studies that successfully use eConsent more efficient? Are more patients participating in these trials for the duration?

We will get there. Fortunately, digital technologies finally enable us to develop reliable measuring sticks and a barometer that can grow more granular and reliable over time. —*Dr. Tenaerts*

Q: What about regulatory concerns over the use of these technologies?

A: There are many regulatory guidelines and rules globally around consenting for trial participation. One to highlight is the current [ICH E6\(R3\) Draft Principles for Good Clinical Practice](#) from the International Council for Harmonization: the third principle in the draft

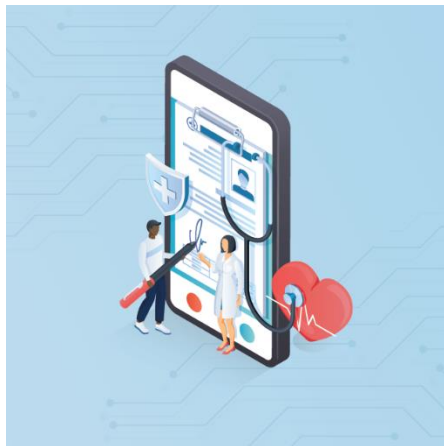
document states, “consent is integrally important for the ethical conduct of a trial.” It now mentions technology as part of this process, showing that regulatory bodies are evolving to support the deployment of eConsent, where applicable. Switching from paper to digital can improve the level of understanding—the “informedness” of this critical process.

When navigating differing regulatory standards, the key is flexibility. A one-size-fits-all system won’t work. For example, in the *Code of Federal Regulations* the U.S. allows for digital signature capture under the regulation called 21 CFR Part 11 for compliant digital signatures, but there are other countries that require wet signatures only (although this is changing). Direct print-to-sign functionality is helpful in the U.S., but an eConsent system must also incorporate a wet ink document upload feature to allow for real-time review and recall of the patient’s digital consenting form. There will also be personal information identifiers included in the system, so you need a system that can handle these data in accordance with each country’s privacy laws and standards. —*Holland*

SITES & SPONSORS

Five Considerations for Sites When Selecting an eConsent Solution

Bree Burks, RN, MSN



How can research site staff manage patient consent efficiently if they are required to use a different system for each study? Learning and using multiple consenting solutions is difficult and adds complexity to research operations, leading sites to rely on manual processes that can delay trials. There is, however, a better way to manage informed consent, and positive change is happening across life sciences because of it.

New electronic consent (eConsent) solutions are transforming the experience for both sites and patients by allowing staff to break free from administrative tasks and patients to provide informed consent from the comfort of home. More investigators are standardizing consent processes across trials by adopting eConsent solutions built specifically to address the challenges sites face every day.

If you need to streamline informed consent for your next study, here are five key considerations to help select the right eConsent solution.

Put the Patient First

Patients participating in trials carry a heavy burden, traveling long distances and investing hours at sites to review consent documents. Because of the time commitment, some patients rush through the review process leading to issues with comprehension. eConsent elevates this experience by simplifying document access and review and enabling customized experiences based on the patient's unique needs. Empowering patients with the ability to access study

documents anywhere, anytime also provides the flexibility to complete consent from the comfort of home and with family or caretakers if needed.

Your eConsent should seamlessly work together with patient-facing applications designed for virtual visits, electronic patient-reported outcomes, and messaging. As more patients interact with clinical trial technology, the objective should be to provide one tool for all engagements.

In addition, eConsent should deliver an easy and intuitive user interface that helps patients navigate and complete the informed consent process. Enabling digital consenting is more convenient for patients and improves the experience of participating in a study.

Identify an eConsent Solution for All Studies

Using a different patient consent solution for every trial isn't optimal because of staff access and usability issues. Every system includes distinct processes and requirements, and the slightest deviation leads to compliance risk. This is a significant challenge for sites as research teams struggle to implement standard operating procedures for consenting when there is so much variation across systems. Selecting a solution that can be used for all studies enables the standardization that drives greater site efficiency and improved study quality.

Ensure the System is Validated

Many sites do not have big budgets or large information technology teams to validate eConsent solutions independently, making validation a critical part of the technology evaluation process. Consider a solution that comes validated for use out of the box. In addition, choosing a system that offers seamless, validated upgrades can ensure ongoing global compliance for sites.

Find the Right Partner

Since you will be replacing previous consenting methods such as wet signatures and study binders with a digital solution, identify a provider with proven expertise at working with investigators. Partner with a technology company that has a reliable history of customer success and is dedicated to innovation. Because of the critical work sites are doing to advance patient health, good isn't enough for technology partnerships—you need great.

Connect Across Systems and Workflows

Prioritize eConsent solutions that connect to existing systems and workflows because they enable faster trial execution. For example, if the solution integrates with an investigator site file, processes can be automated, easing the burden of printing, scanning, and filing paper documents.

The solution should also enable seamless information sharing with sponsors and contract research organizations. This would improve trial oversight and ensure compliance for sponsors while allowing sites to work faster and in a more cost-effective way.

Conclusion: The Shift to Digital Patient Consent

There is no need for research sites to use multiple consenting systems and workflows in trials for different sponsors. eConsent solutions are available now that consider the barriers sites face while completing patient consent, standardizing processes and speeding study execution.

Using a site-first, validated solution means that investigators can digitize the consent process for patients while delivering transparency and visibility to sponsors. By having an eConsent solution that connects to other systems and works across all studies, sites can rest assured that they have the right technology in place to handle any patient consent requirements.

The simple truth is that long forms and legacy systems are no longer sustainable ways for sites to work. To keep up with the requirements of today's clinical trials, patients should be consented using digital, connected solutions. Streamlining and automating informed consent frees up staff, allowing them to shift focus from performing daily administrative tasks to delivering exceptional patient care.



Bree Burks, RN, MSN, (bree.burks@veeva.com) is Vice President, Site Strategy for Veeva Systems. She has more than 12 years of academic medical research experience supporting hundreds of trials spanning all translational stages in sponsor and site settings.

Two Birds, One Stone: Informed Consent and GDPR

Al O. Pacino; Matthew Chandler



With the successful expediting of clinical research for COVID-19, many have questions about the future of clinical research compliance. The challenges of adhering to U.S. Food and Drug Administration (FDA) requirements and new regulations regarding the protection of personal data are ongoing. However, with emerging technology, clinical research executives and staff should be able to adapt more readily. Governments and clinical research stakeholders could work with sites to

include clear data protection agreements required to fulfill the requirements of informed consent and the General Data Protection Regulation (GDPR). It is becoming more possible to harness the digital and decentralized shift of clinical research to better ensure compliance and consent.

Managing the Next Steps

Across the U.S., state legislatures are drafting and/or implementing localized versions of the internationally recognized set of laws known as GDPR. The regulations originated from the European Union (EU) Data Protection Board and outline the ownership of an individual's right to his or her personal information.^{1} The guiding principle of GDPR conveys the importance of data management for every subject's protection and for researchers in EU member countries to safely use GDPR-compliant applications and protection systems. This impacts clinical research sites regarding their handling of subjects' personal information.^{2}

As localized GDPR laws are relatively new, and there is a lot of regulatory overlap between FDA informed consent guidelines and GDPR, many sites may be unaware of their compliance status. Sites able to demonstrate compliance for both sets of laws can leverage their compliant status while also furthering clinical trial progress across the globe.

When comparing the FDA requirements for informed consent to GDPR, there is significant similarity.^{3} For example, the FDA states clinical research participants are entitled to “the confidentiality of information collected during the clinical trial [and] how records that identify the subject will be kept.” This is akin to GDPR’s Article 5, which states, “[Data must be] processed in a manner that ensures appropriate security of the personal data, including protection against unauthorized or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organizational measures.”

Utilizing the language from a compliant informed consent document to create a participant GDPR data protection agreement is a step forward in achieving dual compliance. Minimally, it would benefit sites to update the existing language in their informed consent documents to reflect their obligations in terms of handling a subject’s personal information.^{1,3} It is important to note that research data findings obtained through the clinical trial process are exempt from the right of data access, outlined in GDPR’s Chapter 3.

Several sites could be at or near total compliance with GDPR due to their existing alignment with FDA informed consent standards. The FDA puts a strong emphasis on including information about the role of consent for clinical trial participation. On the topic of consent, GDPR has a detailed section commonly referenced in state laws, under Article 7 entitled “Conditions of Consent.” The section mentions how organizations handle the consent of subject’s obtained personal information. Article 7 states, “Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data.”

When it comes to compliance, sites should be able to more easily implement protocols that allow for addressing both GDPR-like state laws and informed consent obligations. Sites can

signal to other institutions with whom they work, such as sponsors and governments, that being in compliance with both sets of laws means they are better prepared for launching trials. { 1 }

Providing research subjects with a separate document to sign alongside informed consent, under a clear GDPR title, would be necessary as cited by GDPR's Article 7: "If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language." Implementation of a specific document would allow for sites to demonstrate compliance for both GDPR and informed consent.

Continuing to Improve the Process

Digital solutions are becoming more common to advance the social progress being made by the global research community. For many clinical research and healthcare sites, paper-based systems and siloed portal systems that require many logins to conduct clinical trials are being phased out. One of the central drivers for the push to streamline online capabilities is the benefit of distribution capability that comes with single sign-on, cloud/multisystem databases.

Building a larger information system that could warehouse and disseminate regulatory electronic forms could simplify operations-related goals. Ideally, each major type of clinical research stakeholder would be able to access that type of information database from anywhere in the world for the shared goal of maintaining compliance.

Even with existing efforts to modernize the industry, it is becoming more evident the role of stakeholder collaboration is vital. Each stakeholder can benefit from an increased ease of regulatory management and access to up-to-date informed consent requirements. Access to a standardized template for informed consent and GDPR forms should become a viable solution for site sustainability.

An increasingly common practice in healthcare and clinical research sites is the use of electronic forms and signatures. A broader, adaptive solution for all could be having standardized regulatory documents, third-party technical assistance services, and educational courses

available for all stakeholders from one source—this would be setting up a more even playing field for site success.

As our world becomes more interconnected, it is important to make sure we remain open to new industry possibilities. For some, interconnectivity and collaboration seem like a competition liability, but sponsors and contract research organizations are beginning to express interest and even implement more efficient and centralized systems, which were once seen as too risky to start. New collaborative systems allow us to designate responsibility, ensure accountability, and enjoy high-speed access to online learning. Some of the possible outcomes of having an institutional, unified effort are increased site sustainability and faster study start-up. Through increased standardization, everyone can benefit by reducing the stress of regulatory hurdles.

Sites that are open to more innovative business models and those willing to opt into standardized regulatory information access could allow leadership to focus more on team cohesion and study acquisition. If subjects and patients are able to supply their personal information on their phones or tablets, we should consider the abundance of opportunities and not just the initial costs.

Conclusion

Our way of life increasingly relies on new technology; a vast majority of our needs can be managed by simply using applications on our smart phones. One of our greatest capabilities is the ability to distribute an endless amount of information through the internet. To continue producing lifesaving products, it is imperative to harness connective, online tools to distribute the knowledge necessary for sites to succeed. A single location, website, or direct service should be made available to all sites so they can learn about regional privacy laws. Achieving FDA-compliant informed consent and following localized GDPR requirements allow for the opportunity to expand research globally while producing lifesaving products.

Internationally and domestically, social media companies and governments are continuously updating privacy and security standards to better protect individuals. Keeping up is going to require forward and visionary thinking. It is essential that executives use their experience and judgement to apply knowledge around laws that directly impact their research institutions.

Sites that can get ahead and officially declare themselves to sponsors as GDPR- and consent-compliant partners in research can leverage their status to gain an international competitive advantage. All clinical research organizations that can modernize in this way would also reduce long-term risk associated with the penalties and liabilities of noncompliance.

The goal should be to make GDPR and informed consent as easily manageable as possible. Change can sound like potential problems to some, but peace of mind is achievable with the simplified processes and education available through the tools at our fingertips.

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PRESCRIPTIONS FOR BUSINESS

Patient-First Strategy vs. “Pharma Strategy Expertise” for Building Clinical Research Success in Rare and Orphan Disease Treatment

Donvan Quill



Rare diseases affect 1% or less of the global population, with the geographic spread and small number of those impacted making [the cost of research and development](#) (R&D) prohibitive and leaving patients without treatments. Of the 7,000 known rare diseases, [95%](#) thus far do not have a single drug treatment approved by the U.S. Food and Drug Administration (FDA).

Historically, rare diseases have not attracted significant pharmaceutical investment; today, however, that is changing. In fact, large pharmaceutical companies have begun to focus on rare diseases, drawn by government incentives and the growing likelihood that treatments for what are often life-threatening or severely debilitating diseases will be successful.

About [33%](#) of all drugs in active R&D pipelines are now included in the rare disease category, presenting scientific and operational challenges to sponsors and clinical trial ecosystem participants, as well as spurring the adoption of new strategies, operating models, and processes.

Clinical research professionals seeking to build a go-to market strategy, however, may feel overwhelmed about where to start and may be tempted to revert to a so-called “pharma strategy expert.” This term is misleading, given that it’s impossible to provide expertise across the wide range of therapies for rare and orphan conditions. Each patient is unique in terms of the treatment, points of care, physicians, and level of caregiving they require.

Self-appointed rare condition experts may be virtuosos in big pharma or skillful in commercialization strategies with a particular condition, but too often they fall far short of expectations. They offer an ever-increasingly complicated process that fails to be cost effective. What's more, cookie-cutter pharma strategies have no place in today's complex and ever-evolving healthcare environment. What's needed is a patient-first approach that relies on a team of experts who bring a specific understanding to *each patient's condition* to provide effective therapy and care management.

The Downside of Rare Disease Experts

Rare disease “experts” begin with inherent assumptions about care delivery and optimization to map the patient journey. They attempt to break down a strategy into multiple phases, such as precommercial planning and distribution. All of this can be justified with outmoded approaches to care and may sound rational. The problem is that each new phase of the process contains hidden costs and growing complexity with the creation of layers between the clinician and patient that often fail to improve patient outcomes.

In fact, this approach can become so complicated that pharma execs must pay for additional management staff to oversee the process and inform the clinician about next steps in patient services. This not only adds costs and unnecessary layers between the patient and clinician, but also obscures data and outcomes.

When optimizing care for rare and orphan disease patients, the best place to begin is at the end: the patients who require therapy. It's important for stakeholders to learn their individual needs and expectations. They must also understand that compassion—and not managerial layers—is vital for patient quality of life and improved outcomes.

With a patient-first strategy, pharmaceutical manufacturers and their clinical research professionals can build a commercialization team that is open, curious, and empathetic. Patient-first strategies offer targeted programs and services that deliver specialized expertise that transcends the scope of capabilities provided by traditional, legacy care organizations, which are often designed exclusively for scale.

A Patient-First Strategy Mitigates Clinical Trial Disruption

A patient-first approach provides comprehensive, best-in-class services tailored to maximize therapeutic opportunities for people in the rare disease community, including counseling, guidance, and education based upon patient and caregiver needs.

The benefits of partnering with a specialty pharmacy and patient management organization that takes a patient-first approach have been put in bold relief during the COVID-19 pandemic. The best of these organizations use tools to enable in-home clinical services, direct-to-patient support, and remote monitoring for keeping clinical trials on track. This approach can significantly shorten the time from the clinical trial to commercial drug access.

The pandemic represents additional issues facing patients, researchers, providers, and drug manufacturers in the rare and orphan disease market. These challenges include the high cost of clinical trials and patient recruitment. While traditional models are built for scale, a patient-first approach focuses on and customizes services for small patient populations, delivering expertise to overcome the limitations of legacy care models and providing cost-effective programs. This streamlined approach includes financial advantages, assurance that products are properly and promptly distributed, and patient services designed to ensure compliance and quick, accurate reimbursement processing.

Further, integrated telehealth features have enabled patients to get the products delivered without going to the doctor's office. As a result, the trials conducted during the pandemic had significantly more patients involved, despite the national lockdown. This approach helps to build awareness and introduce education programs that aid understanding of patient groups, and clinical research professionals and manufacturers know they have the support to develop a drug and a comprehensive program based upon specific needs.

High Level Support for Specialty Patients

The higher level of care continuity delivered by a patient-first approach strengthens communication, yields rich data for more informed decision making, and improves the overall patient experience. Dedicated clinical teams are better able to seamlessly eliminate treatment

gaps for the patient. This strategy also addresses all variables around collecting data, while maintaining frequent communication with patients and their families to ensure compliance and positive outcomes.

A patient-first care team that includes care coordinators, pharmacists, nurses, and other specialists focuses on the disease state, patient community, and therapy. This is critical for transcending the limitations of the standard specialty pharmacy and hub service provider, which too often rely on technology solutions that fail to address human needs and variability.

Finding the Right Patient Management Partner

When identifying a specialty pharmacy and patient management organization that creates a partnership for personalized care, look for a partner that offers a suite of comprehensive services tailored to maximize the therapeutic opportunities for the treatment of rare and orphan disorders. A patient-first approach can provide the trusted path for patients and all those involved in the treatment journey. This adds much-needed support for the patient's family and caregivers, enabling them to become more engaged and take ownership, which leads to a stronger partnership and better patient care.

Telehealth Considerations

The partner's telehealth solution should be designed to streamline patient enrollment, maximize interaction with patients for adherence and compliance, and provide continuity of care to avoid lapses in therapy. It should rely upon dedicated team members who have expertise in every aspect of the patient's drug and can address every question and concern from patients, pharmacists, physicians, providers, and payers.

Effective telehealth is particularly important for addressing the unique healthcare coordination needs of patients with a rare or orphan disease and, more importantly, the newly diagnosed patient.

As part of a larger personalized care plan, and tied specifically to a particular specialty drug, telehealth enables pharmacists to empower their patients to thrive, even during times of

disruption and uncertainty brought on by the COVID-19 pandemic and other unforeseen emergencies.

Customized care coordination and telehealth solutions add another layer to a proactive, process-driven program, educating the patient on potential risks. This fosters discussion between the patient and providers that is essential to understanding the patient's needs, providing focus on the drug's impact and monitoring overall health. By incorporating assessments and predetermined touch points each month, the care team is able to stay on top of side effects and capture real-world evidence around the therapy, the disorder, and the person's well-being.

Closing Thoughts

On top of everything else already mentioned, the most effective specialty partner should demonstrate expertise in navigating the insurance landscape and prior authorization process, as needed, and know how to monitor and encourage compliance. It's also important to find a partner with dual accreditation from the Utilization Review Accreditation Commission (URAC) for compliance with specialty pharmacy and the Accreditation Commission for Health Care (ACHC) for specialty pharmacy services. This demonstrates commitment to providing quality care and services to these patient populations.

Ideally, the care management solution should meet the needs of everyone involved in the patient's journey, from clinical research professionals and specialty drug manufacturers to pharmacists, caregivers, and physicians.



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RECRUITMENT & RETENTION

Breaking Down Barriers to Oncology Clinical Trial Enrollment Via Artificial Intelligence

TJ Bowen, PhD



Technology is successfully disrupting many industries—but can it help with the systemic challenges of clinical trial recruitment?

Clinical research plays an imperative role in the future of disease detection, diagnosis, and treatment. Fortunately, there's no shortage of innovative therapies being developed by the biopharmaceutical industry. *Unfortunately*, many of these therapies will never reach commercialization because the vast majority of trials designed to test the safety and efficacy of these novel treatments will fail to enroll enough patients to meet critical endpoints.

It is estimated that less than 5% of eligible adult patients enroll in clinical trials. {1,2} This is an extremely small percentage and, given that approximately 15,000 oncology trials are actively recruiting patients, it means that there are not enough patients available. The challenge to enroll is complex and based on a variety of different factors, including demographics/geography (patients must have access to a study site and/or the means to travel); clinical requirements (patients must meet specific and different eligibility criteria for each trial); cultural and

socioeconomic considerations (people of color have largely been underrepresented in clinical trials); and structural limitations (study sites must have adequate staff and other resources to comb through multiple sources of patient data in a relatively narrow window of time to identify a “match”). All of these considerations contribute to low patient enrollment, which in turn means that many patients fall through the cracks and many trials die on the vine.

Historically, large academic institutions have housed the majority of oncology clinical trials; this is primarily a result of their well-established infrastructure and ample resources equipped to support and run trials.^{3} However, more than 80% of cancer patients are diagnosed and treated at community oncology centers, making these sites critical for improving access to care, reducing health disparities among certain populations, and advancing the development of new therapies through the progression of clinical trials.

Barbara L. McAneny, MD, founder and CEO of New Mexico Cancer Center, former president of the American Medical Association, and current board member of the Community Oncology Alliance, believes that community oncology centers will play a significant role in the success of clinical trials moving forward.

“The influence that the community cancer care setting has on the overall drug development and discovery process has not been fully recognized,” said McAneny. “Community oncology centers diagnose and treat the majority of the U.S. cancer population [in communities that] often represent people of color, rural populations, and others who may be overlooked in the traditional clinical trial recruitment process due to geographic and socioeconomic factors. Bringing more trials to the community setting will help increase the quantity of open trials (and their ability to progress) and will ensure that more patients have the opportunity to receive optimal care with cutting-edge therapies.”

The Evolving Complexity of Clinical Trials

The challenge to recruit and enroll is not that patients are unwilling to participate. Part of the problem is finding the right patients for the right trial at the right time when some of the newer, more targeted therapies are involved.

The era of “precision medicine” has ushered in tremendous advances in our knowledge of specific disease areas and how they manifest themselves uniquely in individuals. In oncology, where there are a growing number of precision medicine therapies in development, this has increased the complexity of clinical trials, namely by way of study design and eligibility criteria. This has paved the way for the discovery and development of more targeted therapies, but has also increased the burden on community oncology centers where leaders may not have adequate resources or staff to manage the often challenging and labor-intensive recruitment process.

If a trial is not open at a community site, there have historically been challenges for connecting patients in community settings with clinical trials at neighboring institutions. Additionally, in many cases, community care teams are tasked with deciphering extremely complicated inclusion/exclusion criteria, pulling patient data (often manually) from multiple sources like electronic medical records (EMRs) and lab and genomic data, and engaging with patients in an often very narrow window of time while they are between lines of treatment. This process is frequently organized and data are collected by hand on spreadsheets or (gasp!) sticky notes, resulting in a high likelihood of overlooked or missed patients and, ultimately, failure to fully enroll a trial.

Transforming the Clinical Trial Recruitment Process with Technology

Technology and other automated tools have emerged to help solve many of these problems. For example, a cloud-based clinical trial matching solution powered by artificial intelligence can help identify and match patients to studies for which they are eligible, beginning at the time of diagnosis. Data are ingested and analyzed from multiple sources, including pathology, laboratory information systems, EMRs, and third-party genomic data, and aligned with study protocols to find patients who may be eligible for a specific trial.

A truly advanced matching system provides rich data analysis capabilities to ensure that all patient data are evaluated while its comprehensive workflow system helps to connect all members of the patient’s care team. Ideally, real-time notifications are sent to the patient’s team regarding potential eligibility for trials and time-sensitive alerts remind healthcare teams when a patient has become available.

Conclusion

Technology is not meant to replace the human factor in clinical trial recruitment or general oncology care, but it can dramatically improve efficiencies and alleviate some of the burden that many smaller practices face from a resource standpoint.

It's an exciting time for the scientific community, medical providers, and patients—advances in drug development and technology are starting to change the way serious disease is diagnosed and treated. Doctors and patients have more options. More hope. However, as science and technology continue to progress, so must clinical research leaders. Embracing new tools and resources designed to accelerate trial enrollment and broaden access for more cancer patients will ultimately result in more novel therapies and improved patient outcomes.

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OVER THE TRANSOM

We Want...Information

Gary W. Cramer



When I read the words of the headline above, I hear them in the ominous voice of a bad guy from the opening credits of the old British TV series, “The Prisoner.” In that rather grim show, Patrick McGoohan played a spy being held in a secret village by anonymous forces using every mind-bending scientific method of an ethically dubious nature under the sun to get him to confess to having some “information” they wanted—all without gaining informed consent, I must add.

However, if our beleaguered hero—who is only ever referred to as “Six” by his captors—ever had such information, he wasn’t about to let on about it, preferring to spend the entire series fighting the powers that be and proclaiming “I am not a number! I am a free man!” Stirring stuff for the 1960s, and still a source of inspiration for modern thrillers.

In our present-day clinical research enterprise, much is said about the value of not treating volunteers for studies as mere numbers or sources of information datapoints. True, more and more emphasis is being placed on patient-reported outcomes when evaluating trial results and on patient-centric input when designing trial protocols, but those are matters of making better use of the resources at hand to improve trial conduct rather than trying to get blood from a turnip, as they say.

In that spirit, here are some excerpts from recent news items that crossed my desk about how various organizations are taming information for their own aims in the pursuit of more efficient and rewarding research and development projects (no endorsements implied).

Clinical Translational Science Center Awarded Grant Renewal From NIH

The [UC Davis Clinical Translational Science Center](#) (CTSC) [has received notice](#) of its third National Institutes of Health (NIH) award renewal. The five-year award, almost \$33 million, comes from NIH's [National Center for Advancing Translational Science](#). It provides critical funding to CTSC to continue its essential services for the UC Davis research community.

In 2006, UC Davis received one of the first 12 NIH [Clinical and Translational Science Awards](#) in the nation to establish a center for clinical and translational science. The center supported the full spectrum of translational research (from bench to bedside to dissemination and implementation). It served as a hub for researchers promoting human health. In 2011 and 2016, the CTSC was successfully renewed.

With institutional support to augment NIH grant funding, the CTSC promotes translational research at UC Davis by:

- Training and cultivating the workforce
- Engaging patients and communities in every phase of the translational process
- Supporting the integration of special and underserved populations in research across the human lifespan to promote health equity
- Innovating processes to increase the quality and efficiency of research, particularly of multisite trials
- Advancing the use of cutting-edge informatics

CTSC fosters trainee and scholar success at all career stages. For example, it manages [KL2 awards](#) in support of highly qualified junior faculty conducting mentored, multidisciplinary, patient-oriented clinical research. The CTSC also facilitates better health among underserved rural communities, such as the San Joaquin Valley.

In 2020, the center pivoted to [provide specialized support to research teams conducting studies on coronavirus](#). It enhanced access to digital health data, helped recruit participants, provided regulatory support, and implemented protocols for [many of the COVID-related clinical trials](#).

Reviewing the Top Clinical Research Technology Trends in 2021

According to [a recent blog](#) by Florence Healthcare, “If you want to understand the latest trends in clinical research and the direction the industry is headed, the Association of Clinical Research Professionals is always a reliable resource.” That’s why Florence attended [ACRP’s](#) virtual Operational Efficiencies Conference in May 2021 and assembled some key takeaways about how clinical research sites adapted to a post-COVID world and how technology can make trials more efficient through eConsent, eSource, and remote monitoring, including the following:

- Decentralized clinical trials that use technology to collect data are convenient for patients and effective for sponsors, contract research organizations (CROs), and research sites. However, it’s important to consider which interactions should take place in person and which should be online.
- Sponsors and sites crave technology that’s intuitive, but they also want vendors to provide customer support and training on an as-needed basis. Technology providers should be able to tell users what ongoing support they offer beyond the implementation process.
- An informal poll taken during a presentation from Florence showed that 28% of attendees already had eRegulatory in place, while 38% were evaluating systems and 34% still used paper. Meanwhile, a Tufts Center for the Study of Drug Development survey showed that 63% of sponsors, CROs, and sites anticipated strong use of eConsent post-pandemic, while 56% expected strong use of eSource and 55% expected strong use of remote monitoring.
- Decentralized trials and remote work became far more common during the pandemic, but these trends aren’t going away. With the worst ravages of COVID-19 behind us, clinical trial professionals can now focus on which aspects of remote technology have worked and which need to be improved so they can keep moving toward a more efficient, patient-focused clinical trial industry.

How Low Healthcare Usage and Trust are Tied to Likelihood of Trial Participation

Writing for [SubjectWell](#) recently, Ivor Clarke noted that, “Quality care in any healthcare system relies heavily on patients developing and maintaining trust in their healthcare professionals (HCPs). As we’ve witnessed throughout the COVID-19 pandemic, local HCPs informing and guiding patients on proper treatment and preventive measures were more successful than similar messages pushed from government agencies or medical institutions.” However, while patient trust in HCPs is essential in delivering proper treatment, Clarke wrote that trust does not necessarily extend to positive sentiments regarding clinical research.

In May 2021, SubjectWell polled 892 respondents from South Africa, Canada, and the United States on the topic of healthcare usage, trust, and clinical trial participation. Among the more curious findings from the poll, lower healthcare usage and lower trust in HCPs correlated to higher likelihood of trial participation.

“When we took a closer look at the likelihood of clinical trial participation between countries, South Africa, the country with the lowest HCP visitation rates and lowest overall trust in the healthcare system, responded with the highest likelihood of clinical trial participation at 64%” for a trial unrelated to COVID-19, Clarke wrote. That compared to 59% saying the same in Canada and 54% in the U.S. Similarly, lower healthcare usage and lower trust in HCPs correlated to higher confidence in finding a relevant clinical trial.

To request a download of the complete survey data, visit www.subjectwell.com/surveys.

Company Secures \$4 Million to Expand Availability and Adoption of AI-Powered Platform

In June, BEKHealth [announced](#) \$4 million in funding to accelerate the adoption of the company’s clinical research software platform. BEKHealth’s artificial intelligence (AI)-powered platform aims to accelerate and improve clinical research processes by combining electronic medical record data processing, feasibility and site selection, precision patient trial matching, and care coordination. The company says its AI models combine more than 400 unique medical libraries and 70,000 research protocols with an interoperable clinical data model to power its clinical research software platform.

Powering COVID-19 Studies with a Global Decentralized Clinical Trial Platform

Castor, a provider of clinical trial technology, announced in late May continued rapid adoption of its free [decentralized clinical trial platform](#) for COVID-19 research projects. The company says it is supporting more than 250 COVID-19 studies in 40 countries across 1,750 hospitals. 62,000 participants are enrolled in these trials and more than 139 million datapoints have been captured. The company has also developed pre-built electronic case report forms based on World Health Organization (WHO) standards, to help researchers start their study or registry in less than an hour and saw emergency COVID-19 projects go live within 6.5 days on average. One example

of a study powered by the eClinical suite is [WHO's Solidarity trial](#), the largest adaptive COVID-19 clinical trial ever conducted, and one of the largest international randomized trials for COVID-19 treatments, having enrolled more than 13,000 patients in 500 hospital sites in more than 30 countries as of the company's announcement.

Scaling Up eConsent

Circling back to this issue's theme on informed consent, Signant Health shared six important factors to keep in mind when implementing eConsent at scale across drug development portfolios in [a recent article](#). "The benefits of eConsent are well understood," the article notes, "and regulatory questions [are] very addressable by good solutions with flexible features. Greater benefits can be observed by scaling the use of eConsent from select studies to use across the portfolio."



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