The revised Common Rule, scheduled to take effect July 19, includes new requirements for the structure of informed consent documents, including that they begin with a concise presentation of the form’s essential points — a change that could turn the form into a tool that can help guide a patient’s clinical decision-making.

Under the new regulations, sponsors must include upfront statements and explanations: how consent is being sought for research, and that participation is voluntary; the purpose, expected duration and procedures of the study; the reasonably foreseeable risks and discomforts; the potential benefits; and any alternative treatments available.

“Many of us view this provision as one of the most important innovations to the regulations, and we think it has a huge potential for improving the system,” said HHS Office of Human Research Protections Director Jerry Menikoff, during a March 14 meeting of the HHS Secretary’s Advisory Committee on Human Research Protections, which was tasked with exploring the impact of the new regulations on the research community.

The most common complaints about consent forms have been that they are too long and unwieldy, with large portions acting as boilerplate, or written vaguely enough to apply to any trial, Menikoff said. He compared other forms to television advertisements for medicines, with

By Conor Hale

Best Practices in Site Feasibility Studies Can Set the Stage for a Healthy Trial

Well-performed, confident site feasibility studies, at times a tedious, thankless task, can become the single most important factor in reducing costs and time spent during a clinical trial, according to Wes Martz, associate director of ePharmaSolutions’ clinical services division.

Leading causes of study delays and busted budgets — startup timelines, enrollment issues and attrition — can be mitigated through a comprehensive, centralized and transparent site evaluation process, said Martz, during a WCG webinar on best practices.

In addition, crowdsourced feedback from feasibility surveys can give sponsors, CROs, service providers and investigative sites the opportunity to re-calibrate their operations.

With wider adoption of benchmarking and other clinical trial management tools, sponsors know exactly how many sites they may need, which the turns feasibility process into what is essentially a job interview, he said. That makes site pre-identification essential for efficient study startup.

Sponsors should evaluate potential sites’ past recruitment and retention of the patient population, Martz said, including their track records in enrollment. A site’s infrastructure, data quality and startup timelines, as well as any additional IRB or ethics committee requirements, should also be considered.

By Conor Hale
**Industry Briefs**

**Veeva and Six CROs Form New Industry Data Standards Group**

Veeva Systems and six large contract research organizations formed a new technology standards group focused on improving trial collaboration with sponsors. The group — dubbed Align Clinical CRO — includes ICON, Medpace, Pharmaceutical Product Development, PRA Health Sciences, Syneos Health and UBC. “There is tremendous potential to enhance clinical trial execution with common technology standards that benefit the entire industry,” said Henry Levy, president of Align Clinical CRO, which aims to reduce operational costs and run trials faster. “By creating a vehicle for CROs to collaborate and share actionable insight with sponsors, we can improve operational delivery and streamline the increasingly complex trial process,” said Syneos Health CIO Rachel Stahler. The group expects to first deliver a pre-competitive operational data exchange standard, to facilitate information sharing between sponsors and CROs, including definitions related to trial operations, key metrics and milestones. The standard will be posted for public review and input before adoption, the group said. “This is the first time CROs are coming together to make this commitment to transform clinical trials across our industry, and we are excited to be part of this effort,” said Michael Brooks, executive vice president of product registration at PRA Health Sciences. “This shows our mutual commitment to make the drug development process more efficient and to help bring needed therapies to market more quickly.”

**FDA Releases Guidance for Using COPD Patient-Reported Outcome Tool**

The FDA finalized the guidance for sponsors and researchers on how to efficiently use the St. George’s Respiratory Questionnaire, a self-administered patient-reported outcome tool, in clinical trials of treatments for chronic obstructive pulmonary disease. If the questionnaire is to be used for trial population stratification or enrichment purposes, it should be discussed with the FDA review division early in the protocol development phase, the agency said. The SGRQ can also be used to assess efficacy in IND, NDA and BLA submissions as a co-primary or secondary endpoint. The scoring uses three elements: the frequency and severity of symptoms, the effect of the disease on common daily physical activities and the psychological impact. Sponsors should only use the total score to measure improvement, with the minimum clinically important difference being four units on the SGRQ scale. The agency said there is no evidence to support the use of other values. Responder analyses can be presented as the responder rate for each arm and the difference in rates, or as an odds ratio. Other analyses may be suitable and should be discussed with the review division. The agency said it considers SGRQ information to have clinical importance, and recommended sponsors report data regardless of the results. The full guidance is available here: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm071575.pdf.

**WCG Acquires ACI Clinical, Adding Safety Monitoring and Trial Advisory Services**

WCG Clinical Services Division acquired ACI Clinical, a provider of endpoint adjudication and data safety monitoring committees. ACI will continue to operate as an independent service organization within the clinical services division, with capital, regulatory and corporate support from WCG. Financial details about the transaction were not disclosed. ACI’s global network of more than 500 medical, statistical and safety experts can now serve as committee members and advisors to WCG clients, said WCG Chairman and CEO Donald Deieso. ACI plans to work with clinical trial sponsors, academic experts and regulatory agencies to enhance trial integrity, reduce variation in important clinical trial events and enhance patient safety, said Jonathan Seltzer, president and CEO of ACI.

**CDISC Receives $1 Million Grant to Develop Type 1 Diabetes Standards**

The Clinical Data Interchange Standards Consortium, or CDISC, received a $1 million grant from the Leona M. and Harry B. Helmsley Charitable Trust to develop new data standards for clinical trials in type 1 diabetes. “Tools that facilitate standardized clinical trials and studies are enabling crucial data sharing and are essential to achieving our goal,” said Gina Agiostratidou, director of Helmsley’s type 1 diabetes program. The new standards plan to offer machine-readable metadata in pediatrics, devices, prevention and exercise. CDISC will work with the Critical Path Institute to pilot the use of large datasets in the development process. CDISC standards, developed for more than 30 disease areas, have been adopted in over 90 countries, and are required in submissions to U.S. and Japanese regulatory authorities. The standards will be freely available on the CDISC website.
Informed Consent (continued from page 1)

wonderful, colorful descriptions of the drug's potential benefits and then buried, compressed lists or grids of possible risks, ad nauseam.

OHRP has said, for example, that a complicated clinical trial involving cancer patients with 20- to 25-page-long consent forms may have a key information section of no more than a few pages. A 10-page description of potential risks, accompanied by complex charts and graphs, however, would not satisfy the rule's requirements to be concise and focused, they said. While it does not strictly specify the types of information that should be included, OHRP said it expects sponsors to keep the new sections relatively short, and summarize the more detailed information found later in the consent form.

“The overall purpose of the changes to the consent provisions, at heart, is to be truer to the ethical underpinnings of the regulations... giving a person the information they need to make an enlightened decision,” said Jerry Menikoff, Director, HHS Office of Human Research Protections.

However, the mandated changes might not have any effect on shortening the overall document, said David Forster, a member of the SACHRP harmonization subcommittee and chief compliance officer at WCG, who described the new requirements as additive.

“It will probably lead to consent forms that are as long, perhaps longer — but if we do this correctly, they will be more understandable to subjects,” Forster said. “No previously existing elements in the current rule were removed,” he noted.

SACHRP member Nancy King said she hopes the new regulations motivate sponsors to think about the clarity of the rest of the consent form.

“What we don’t want is to give directions on how to do this beautiful key information section, and then just have them plop 25 pages of bulleted, unstructured lists after it,” said King, a health policy professor at Wake Forest University.

“I have to say, we talked about length as long as I can remember, and they keep getting longer,” said Stephen Rosenfeld, chair of SACHRP, describing how the key information requirement is a signal of giving up, in a way, of trying to simplify the process.

“There are going to be these drivers — whether they’re liability concerns, compliance concerns or other things — that have stood in the way of us making better, more streamlined consents in the first place,” said Rosenfeld, chair of the executive board for Quorum Review IRB.

“So now we’re going to put all of those things aside, and build a tool that will be part of the consent process that will be focused explicitly and only on participant decision-making,” he said. “If there are side effects that improve the rest, that’s great — but we’ve been trying to do that for an awfully long time without success.”

Hours before the new Common Rule was scheduled to go into effect January 19, the federal government pushed back the implementation date by six months to July, with the possibility of enacting further delays.

However, companies can begin implementing certain provisions of the new rule before the deadline — such as the informed consent key information requirements — because the changes are not prohibited by and do not conflict with current law, according to the OHRP.

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Site Feasibility (continued from page 1)

While the ability to recruit patients is at the top of the list, sponsors should also plan for the entire life of the study, including any possible future effects on accrual — such as whether or not the principal investigator is a specialist that patients may regularly see outside of a clinical trial, where they may feel more comfortable.

In one example, a study of a respiratory syncytial virus vaccine had its site feasibility initiative focused solely on the ability to recruit — which made some sense, considering the trial required patients be enrolled within one to two days after birth, through NICUs and neonatologists, Martz said.

“The problem, of course, became clear very soon,” he said. “The mothers didn’t want to bring their babies back to the hospital on a regular basis. They had planned to bring them to their family physician or pediatrician.”

“It’s important to think about how the whole patient pathway works — not just up to enrollment, where you can grab them and provide the opportunity for the trial to the patient — but also to conduct that study ongoing,” he said. Sponsors should keep an eye on whether patients are going to be more likely to regret participating later in the process, because they’ve committed to treatments they otherwise wouldn’t have, and may feel like they’re not getting any additional care.

Sponsors should tailor their communication and outreach strategies based on their product, study and scenario, as sites may receive dozens of feasibility surveys and questionnaires at a time. In return, sites can make themselves stick out from the pack by taking the opportunity to provide thoughtful responses and express enthusiasm for the scientific project.

Communicating with sites before they receive the invitation leads to higher response rates and faster turnaround times, Martz said. Even larger pharmaceutical and biotech firms that can bank on name recognition and established relationships with sites, can reduce the time needed to fill out questionnaires by more than half by communicating early, he said.

Small companies, or companies with a nascent intellectual property, may need to cast wider nets and market the product by sharing articles or even early study results. Educating the site personnel about why the product is exciting, possibly through doctor-to-doctor communications, can increase response rates significantly.

Now, the so-called “boring” studies — such as FDA-mandated postmarket trials, those with an unmotivated patient population or trials that simply do not pique the scientific interest of investigators — may require more of a site recruitment effort, Martz said.

Sponsors should broadcast any perks for sites that decide to participate: such as new technologies being utilized, cutting-edge trial management systems and the possibility for remuneration. Describing the study as “well-funded” can be a successful tactic, he said.

Feasibility questionnaires should be designed for the best experience by the sites and the end user, and the shorter the better. In some cases, this is a site’s first indication of how your company does business, Martz said. Long, disjointed questionnaires with redundant questions seeking irrelevant information can be frustrating, making sites more reluctant to work with the sponsor in the future.

The format of the survey also can increase response rates. Questionnaire responses can be pre-populated into the form to minimize the chance for varied or incorrect interpretations of the questions, but sponsors should allow for qualifiers or explanations in critical sections.

Wherever possible, it’s helpful to ask for hard, whole numbers — such as patient counts — instead of asking for percentages, which can give sites a license to make guesses, Martz said.

Sponsors should build a database of the responses they receive, to help pre-identify sites the next time around. It also lessens the burden on sites by eliminating the need to have them enter the same information repeatedly.

Meanwhile, a centralized reporting process can be scaled up to encompass a global feasibility initiative, and provide study leadership real-time views of site-level responses. It can also promote transparency and accountability for any decisions to proceed, Martz said, as well as foster a collaborative approach to the process.
The Pulse on Study Conduct  By Elizabeth Weeks-Rowe

No one can dispute the impact of technology on clinical research. eConsent interactively educates study participants on the study risks, benefits and responsibilities of trial participation, while clinical researchers have had to discard archaic means of data collection that imposed parameters on time and convenience, in lieu of electronic-based systems that truly engage and enlighten the modern study patient.

I have always considered informed consent the most important aspect of the clinical research educational process because I was involved with consenting patients early in my clinical research career. Beyond any preliminary dialogue between a physician or study patient, the informed consent form (ICF) is the fundamental educational bridge between study interest and study participation, between research theory and research application. This 15-30-page paper document illustrates everything about the study, with the ability to sway a human heart and decision process with the language therein.

When I was a study coordinator, the study patient we were consenting was allergic to a component of study drug, which was discovered during the study drug expedient overview from the informed consent form. That experience instilled the critical need to assure beyond all reasonable doubt that the study patient received every piece of information required for them to make an equitable decision, to allow them to truly consider whether the risks outweighed the benefits of study participation.

Further, that experience framed all subsequent ICF reviews as a CRA and inspired me to check the printed names and signatures of study patients against the delegation log, motivated me to confirm that sites had an ICF SOP or appropriately documented ICF process and moved me to check ICF content beyond the initials/signature pages to ensure that updated safety or treatment data had been included. In my career as a clinical researcher I have contributed to ICF error, ICF issue resolution and helped ensure that IP risk language was present in large consent applications.

At present, patient consent management is becoming eConsent. My first personal encounter with eConsent was at my physician's office. I was given a tablet with which to review and electronically sign the informed consent, (for the elective procedures I was having) and I was intrigued. The tablet consent described the procedure in the most basic terms, and required electronic confirmation of page review before allowing me to proceed to the next page. It was a preliminary demonstration of an educational tool with vast capabilities for patient teaching/comprehension, but I did not fully realize it at the time.

During a site selection visit, the very progressive research-dedicated site had recently implemented an eSource and eConsent system. The consent was built within the platform and delivered via tablet, with hyperlinks and interactive media to further explain the study drug, patient responsibilities and risks/benefits. The platform had versioning control to ensure the patients were consented with the correct ICF version and the patient's electronic signature was time/date stamped to assure authenticity. However, the most dramatic benefit was the educational process. The patients were immersed in the ICF process instead of being poised hesitantly at the sideline of understanding. They were given every tool to make an informed decision regarding study participation, and with patient safety heading each discussion. It was inspiring to hear the site manager describe the process and how it had succeeded at their site.

eConsent affords the patient the ability to be engaged, proactive and more informed. It encourages increasing the number of study participants and reduces the risk of study drop-outs. It affords the site a competitive advantage technologically, increases enrollment and decreases compliance risk.

I believe eConsent has the potential to exponentially improve the study patient's education and remove additional barriers to understanding. I recently participated in an educational webinar about eConsent and the many benefits of the platform, primarily the impact on patient awareness and understanding, as well as electronic confirmation that they were provided a GCP-compliant process. The webinar demonstrated the positive impact technology can have on the study patient's research experience and assurance of safety. This experience gives me the reassurance that, despite any great changes to come in the world of clinical research, patient safety and education will remain the primary foundation of the new frontier.

Elizabeth Blair Weeks-Rowe, LVN, CCRA, has spent nearly 14 years in a variety of clinical research roles including CRA, CRA trainer, CRA manager and clinical research writer. She also is author of the novella Clinical Research Trials and Triumphs. Currently she works in relationship development/study startup in the CRO industry. Email ebwcr@yahoo.com or tweet @ebwcr.
### Drug & Device Pipeline News

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Ionis and Akcea Present New Data from ATTR Amyloidosis Program

Ionis Pharmaceuticals and its affiliate, Akcea Therapeutics, announced Phase III data showing that inotersen-treated patients with hereditary ATTR (hATTR) amyloidosis who were treated for up to 27 months in the NEURO-TTR and open-label extension (OLE) studies continued to demonstrate sustained benefit in measures of quality of life and neuropathy. The NEURO-TTR study was a Phase III randomized (2:1), double-blind, placebo-controlled, international study in 172 patients with polyneuropathy due to hATTR. The 15-month study measured the effects of inotersen on neurological dysfunction and on quality-of-life by measuring the change from baseline in the modified Neuropathy Impairment Score +7 (mNIS+7) and in the Norfolk Quality of Life Questionnaire-Diabetic Neuropathy (Norfolk QOL-DN) total score. The NEURO-TTR OLE is an ongoing study for patients who completed the NEURO-TTR study and is intended to evaluate the long-term efficacy and safety profile of inotersen. Significant benefit was observed in inotersen-treated patients with cardiac disease at baseline in both primary endpoints (Nordic QoL-STD, p=0.036 and mNIS+7, p<0.001) and in the way they felt and functioned in the SF-36 Health Survey endpoint (p=0.025) at 15 months, compared to placebo.

Ablynx Announces Results From Systemic Lupus Erythematosus Study

Ablynx announced that the Phase II dose-ranging study of vobarilizumab, the Company’s anti-IL-6R Nanobody, did not meet the primary endpoint of dose response based on the modified BILAG-based combined lupus assessment (mBILAC) at Week 24. This multi-center, randomized, double-blind, placebo-controlled, dose-range finding Phase II study enrolled 312 patients with moderate to severe, active seropositive SLE across the U.S., Europe, South America and Asia. The study enrolled patients across five treatment arms (four dose regimens of vobarilizumab and placebo). Safety findings through Week 58 were favourable for vobarilizumab. Treatment-related serious adverse events were reported in 2.0 percent of all vobarilizumab-treated patients compared to 6.5 percent in the placebo group. The percentage of patients experiencing a serious infection was also lower in the vobarilizumab arms compared to the placebo arm (2.8 percent versus 6.5 percent).

Allecra Therapeutics Announces Positive Results from Phase II Study

Allecra Therapeutics announced positive top-line results from the Phase II study of its lead antibiotic candidate, AAI101. The Phase II CACTUS study (Randomized, Double-Blind, Multi-Center Study of Cefepime/AAI101 in hospitalized adults with Complicated UTIs) met all study objectives. AAI101 was given intravenously to patients in combination with cefepime for the treatment of cUTI including acute pyelonephritis (AP). The study was designed to determine the optimal dose of cefepime/AAI101 to be taken forward into future Phase III studies. 45 patients were randomized 2:1 into two cohorts, each with a separate control. Patients randomized into Cohort 1 received either 500mg of AAI101 combined with 1g of cefepime (n=15), or 1g of cefepime monotherapy (n=7). Patients randomized into Cohort 2 received 750mg of AAI101 combined with 2g cefepime (n=15), or 2g of cefepime monotherapy (n=8). Dosing was conducted intravenously three times daily for seven to ten days.

Novartis Reports Data on Secondary Progressive MS Study

Novartis announced the full results from the Phase III EXPAND study of oral, once-daily siponimod (BAF312) in secondary progressive multiple sclerosis (SPMS). The EXPAND study is a randomized, double-blind, placebo-controlled Phase III study, comparing the efficacy and safety of siponimod versus placebo in people with SPMS. It is the largest randomized, controlled study in SPMS to date. The results show significant reductions in the risk of three- (primary endpoint) and six-month confirmed disability progression with siponimod versus placebo and favorable outcomes in other relevant measures of MS disease activity. Full data from EXPAND show that siponimod reduced the risk of three-month confirmed disability progression by a statistically significant 21 percent versus placebo (p=0.013; primary endpoint); efficacy was consistent across many pre-defined subgroups. Other clinically relevant endpoint data show that siponimod reduced the risk of six-month confirmed disability progression by 26 percent (p=0.0058) and slowed the rate of brain volume loss by 23 percent (relative difference; mean across 12 and 24 months, p=0.0002), when compared to placebo.
Upcoming Event Highlights

Conferences
MAY 10, 2018
**West Coast Symposium on Expanded Access**
An all-day event for the drug, device, diagnostics and clinical trial communities. An all-star cast of presenters will probe Expanded Access from every angle — regulatory, scientific, business, patient safety and liability.
San Francisco, CA

[ VIEW ALL CONFERENCES ]

Training Programs
MAY 1-31, 2018
**Program Phlebotomy Training—Two Day Training**
Various locations

[ VIEW ALL TRAINING PROGRAMS ]

Interactive Workshop
APRIL 10-11, 2018
**Clinical Quality Assurance: Roles and Responsibilities for Auditors and Managers**
Learn what FDA investigators use to evaluate your sites and how to develop risk-based CQA processes and compliance readiness.
Cambridge, MA

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Webinars
APRIL 23, 2018
**Managing Cybersecurity Risks in the Medical Device and Healthcare Sectors**
Do you know what the FDA, HHS, DHS and global regulators are planning? The cost of ignorance could include regulatory sanctions and liability judgments and cybersecurity attacks are only growing.

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