New Clinical Trial Guidelines Push for Broader Inclusion of Patients with Brain Metastases

By Conor Hale

With newer systemic oncology medicines beginning to demonstrate more activity within the brain, clinical trial designs need to be optimized to appropriately include patients with brain metastases and gather more reliable efficacy data, according to Response Assessment in Neuro-Oncology Brain Metastases, or RANO-BM.

While patients with active central nervous system disease are often excluded entirely from clinical trials of solid tumors, the group’s new trial guidelines provide recommendations and scenarios for when they should be included early in the clinical development process.

Previously, denying patients with brain metastases from clinical trials would discount half to two-thirds of potential late-stage populations. The researchers also cited a survey of over 400 clinical trials that showed only 41 percent enrolled patients after they had received CNS-specific treatment.

The RANO-BM guidelines also explored the limitations of retrospective studies of CNS efficacy data.

“Although CNS radiological response in a small number of patients might be encouraging, the conclusion that a drug has so-called CNS activity should not be reached without additional data,” the group wrote. Specifically, retrospective studies can overestimate the impact of a therapy, after characterizing CNS disease as non-target lesions.

FDA & CTTI Launch Patient Forum to Boost Engagement in Drug Development

By Conor Hale

The Patient Engagement Collaborative is gearing up for a launch in early 2018. The new, external panel is being built by the FDA and the Clinical Trials Transformation Initiative (CTTI), a public-private partnership between the FDA and Duke University. The panel will act as a forum for discussing new methods to increase patient participation in the agency’s decisionmaking process. It will provide input on incorporating patient-preferences into reviews of medical products and trial protocols to make patient engagement an integral part of drug development.

At the agency, the project will be spearheaded by the newly created Patient Affairs Staff, which coordinates agency-wide patient engagement efforts, best practices and outreach, and promotes public awareness of the agency’s work.

CTTI Executive Director Pamela Tenaerts said that engaging patients as equal partners in development is critical to the success of the clinical research enterprise. She believes researchers too often assume what patients think or would like have happen.

“It’s always better to understand each other’s perspectives,” said Tenaerts.

The new Patient Engagement Collaborative, combined with the FDA’s patient-focused drug development meetings and the Patient Preference Initiative, will lead to improve-
OMB Issues New Notice on Common Rule Delay
The OMB Office of Information and Regulatory Affairs (OIRA) posted a notice on its website Jan. 5 noting that OIRA is reviewing a final rule titled “Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects.” This notice follows but does not replace an October posting noting the review of a proposed final rule titled “Federal Policy for the Protection of Human Subjects: Proposed 1-Year Delay of the General Implementation Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Year” suggesting a more general delay of unknown length. The three provisions were not specified in the listing. It’s currently unclear whether either rule will be published as a final rule before the Jan. 19, 2018, implementation date. Read the posting here: www.reginfo.gov/public/do/oeDetails?rpid=127821

ClinicalTrials.gov Updated To Allow Better Geographic Searches
ClinicalTrials.gov has been updated to include additional local search functions, a new glossary feature and redesigned study record pages. The homepage allows visitors to limit searches to currently recruiting studies, or studies planning to recruit participants in the future. Results also can be filtered to within range of a specified city, making it easier for potential participants to find open and accessible clinical trials. The National Library of Medicine, which maintains the online database, described the changes as the first in a series. Future updates will be listed on a What’s New page. The glossary allows users to look up frequently used terms and definitions without navigating away from the page, although sponsors and investigators should continue to refer to the Data Element Definitions documents for the items required for submissions, the NLM said. A new Results Submitted tab allows users to track the quality control review process conducted by NLM staff. Information submitted by sponsors and investigators is not posted until all major issues, including errors, deficiencies or inconsistencies, have been addressed. A table of dates outlines submitted data and NLM review cycles. In addition, study record pages now contain a link to Key Record Dates for tracking milestones such as trial registration, posting of results and clearing QC criteria. The record page layout was also redesigned to make the most important information more prominent.

FDA to Commit to Faster Scheduling of End-of-Phase Meetings
In a new draft guidance, the FDA committed to faster scheduling of end-of-phase meetings with applicants, down to two weeks instead of three, while moving up deadlines for related meeting packages. The document also outlines standardized procedures for requesting, preparing, scheduling, conducting and documenting interactions with the agency. Of the four types of formal meetings that can be requested, Type A meetings cover important safety issues or stalled development programs, such as dispute resolution meetings, clinical holds and meetings following a refuse-to-file letter. Applicants can expect responses to Type A requests within 14 days. Type B meetings include pre-IND, -NDA or -BLA meetings; emergency use authorizations; REMS or postmarket requirements; and the meetings afforded by a breakthrough therapy designation. They are typically granted within 21 days. Type B previously included end-of-phase meetings, as well as meetings leading up to the launch of Phase III clinical trials. They are now considered “Type B (EOP)” meetings, with 14-day goals. Type C meetings, meanwhile, cover any other request from an applicant, at 21 days. During the meetings themselves, the new guidance now states that FDA policy prohibits audio or visual recording of discussions. FDA minutes are the official record of the meeting, which are issued within 30 days. The draft guidance on meeting requests is available here: www.fdanews.com/12-28-17-FormalMeetingGuidance.pdf.

INC Research/inVentiv Health Becomes Syneos Health
INC Research/inVentiv Health has changed its brand identity to Syneos Health (pronounced SIN-ee-ohs). The company’s integrated platform leverages a combination of clinical and commercial solutions. For example, behavioral insights are leveraged to accelerate clinical trial recruitment, and therapeutic know-how infuses multi-channel commercial programs to better engage increasingly hard-to-reach stakeholders. All of these solutions are designed to improve the likelihood of launch success. Syneos Health common shares are expected to trade on the Nasdaq Global Select Market under the new ticker symbol “SYNH” by January 9, 2018. Until then, Syneos Health will continue to be listed under INC Research Holdings, Inc. and the symbol “INCR.”
Medical knowledge for the vast assimilation of clinical research guidelines is necessary for anyone entering the field. The diverse regulatory landscape requires us to stay abreast of changes that impact patient safety data. It is a multifaceted learning process with educational requirements that vary by role. We should never expect anyone to have every answer, or to know everything about a protocol/therapeutic area. That sets an unrealistic standard that undermines performance.

Whenever assigned to a new study therapeutic area, I prepare enough to effectively discuss the trial design, study drug and eligibility criteria with investigational staff during site assessment. I want to provide critical details beyond the protocol so that they can make an informed decision regarding their capabilities for study participation. The extent to which I learn the therapeutic area is more than what is expected for a preliminary study discussion, but this ensures sponsor and site satisfaction.

Many years ago, I was assigned to select sites for a rare disease study. The first investigators with whom I was scheduled to meet were therapeutic experts; M.D./Ph.D.s who had advised on trial design, compound development or both. It was a brand new clinical area for me, and while eager to learn, I also felt trepidation over presenting to clinical experts as a novice. The study project manager repeatedly informed me that every investigator and site visit was high-profile. However, nothing was as important as the first study meeting at the site scheduled for first patient screened. This critical milestone hinged on this site, and the magnitude portrayed by the study manager's email instruction for the meeting read like the declara-
tion of independence to colonial Americans. “Exceptionally important site to the sponsor!” “Focus only on high-level information due to expertise!” “Confirm eligibility potential of first patient screened!” “Gently encourage the site to provide the first screening date!”

In other words, I was to present the protocol to the M.D. scientist who had helped design it, confirm their patient met eligibility criteria, and gently urge them to rapid screening in an area where they were international experts and I was the beginner, when they had a direct line to the sponsor and I communicated through an overwhelmed study manager.

Without realizing it, I was allowing the study manager's panic to influence my impression of these investigators, to create worry where good judgement usually prevailed, and to rethink an organized process. This changed my usual process in that I found myself up to the late hours Googling every diagnostic term, re-reviewing the protocol and attempting to memorize inclusion/exclusion criteria. And for what? To serve a preconceived impression of an investigator that was formed under duress and may or may not be correct?

My good sense convinced me to shut down my computer and trust that I had prepared to the best of my ability. I could only control my reaction to the unknown and my professionalism should I be given a lukewarm reception.

The next morning, I arrived at the imposing university hospital ahead of schedule. I waited in the lobby until the study coordinator appeared to escort me back to the conference room. An individual I presumed to be the principal investigator was sitting at the conference table reading email on his phone. Before I could do so he extended his hand warmly and introduced himself as the study co-investigator. I recognized his name from the protocol as he had been quoted several times in the footnotes. He was a specialist in the indication but treated the patients in clinical practice more frequently than the principal investigator, who spent more time behind the podium speaking/lecturing or under the microscope studying new treatment. He then proceeded to shatter any preconceived notions with his wit and we formed an instant rapport.

Several minutes later the principal investigator arrived and apologized for being late. I introduced myself, and he smiled and graciously thanked me for coming to their site. As I flipped to the start of the protocol slide deck, I informed the investigator that I was going to cover only high-level information due to his expertise. The Principal Investigator's response surprised me more than his colleagues had. He asked me to please cover everything that was required to adequately conduct the visit. He offered to supplement the protocol information with specific data from the earlier trials, if I was interested.

After I reviewed the study information I asked the investigator about his plan for identifying patients. The indication was rare and the enrollment process was expected to be laborious due to this. The investigator provided a comprehensive plan for patient identification that included genetic databases and area colleague referral. He had clearly deliberated the process with his team, which accounted for his transparency, as opposed to rote proclamations of enrollment prowess based on expertise.

The meeting was extremely positive. Both investigators were appreciative of the information I provided and happily answered all my questions. They were self-effacing, funny, and gracious. An important lesson beyond the new therapeutic area was learned by me that day. Judge the package by the content and not the cover.

The Pulse on Study Conduct  By Elizabeth Weeks-Rowe

Tips for presenting/monitoring a new therapeutic area

- Review the disease area beyond the protocol. Become knowledgeable enough to speak the language of the therapeutic indication.
- Do not be reluctant to admit that you do not know the answer to a question. The purpose of medical is to answer complicated therapeutic questions. Ensure that you are clear with the question the investigator is asking. Do not be reluctant to ask for confirmation or clarity.

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. Email ebwcra@yahoo.com or tweet @ebwcra.
Clinical Trial Guidelines  (continued from page 1)

“With so many patients with active CNS disease frequently excluded from clinical trials, direct evidence of the CNS activity of a drug cannot reliably be obtained,” the authors wrote, adding that information about a drug’s potential activity must be considered at the forefront of trial design.

The guidelines, published in the January 2018 issue of The Lancet Oncology, describe three scenarios: when study agents are considered likely to demonstrate CNS antitumor activity; when that is unlikely; and when their potential is unknown.

If a drug is considered very likely, the study’s goal should be to generate a robust CNS efficacy signal as well as a systemic signal. This would include mandatory baseline CNS imaging in all patients, and conducted as frequently as systemic imaging, the guidelines said. Sponsors should also clearly specify CNS-related endpoints separately from overall or extra study endpoints.

Drugs that fall under this scenario should have prospective or retrospective data showing CNS responses with the same dose or schedule in the same subtype of cancer. In addition, data from trials demonstrating improvements in non-progression-related CNS endpoints would be helpful.

Depending on the strength and reliability of previous evidence, developers can consider a step-up inclusion design for their clinical trials, moving from including asymptomatic patients to symptomatic, after gathering preliminary efficacy data.

For drugs that are unlikely to be effective against brain metastases, the aim is to minimize risks to patients with active disease, while maintaining the largest possible population of patients eligible to participate in the trial.

Here, baseline CNS imaging could be reserved to primary cancers with a high risk of brain metastases. Re-imaging can be limited to clinically indicated patients, although the guideline recommends follow-up CNS imaging at a lower frequency than systemic imaging.

Patients with treated, stable or no CNS disease can be included, as long as their previous therapy was completed at least one month prior to enrollment, and they display no evidence of radiographic progression. In addition, any CNS disease should be asymptomatic for two weeks.

Sponsors should work to determine any unknown CNS potential as quickly as possible, the guideline said, and to leverage Phase I development, including substudies for patients with untreated metastases, treated at the recommended Phase II dose or schedule.

Later-phase studies could include an early CNS cohort with measurable, untreated, asymptomatic disease. Protocols could be modified as data on CNS potential is gathered to inform future development paths, they wrote.

Broadening clinical trials eligibility criteria has been a work in progress, with some describing it as a necessary culture change.

A recent initiative from the FDA, the American Society of Clinical Oncology and Friends of Cancer Research explored templates for clinical trial protocols that could help increase accrual without diluting efficacy.

In addition to brain metastases, the project tackled other traditional areas of exclusion criteria, including HIV and AIDS, organ comorbidities, age requirements and prior and concurrent malignancies. The templates were developed by a panel of agency representatives, government scientists, academic researchers and members of the pharmaceutical industry.

“We’ve all become comfortable and change has to start someplace — not white papers,” said Edward Kim, chair of solid tumor oncology and investigational therapeutics at the Levine Cancer Institute, during 2016’s launch of the project at the Friends of Cancer Research annual meeting.

Kim described how much of today’s exclusion criteria are seen as boilerplate — grandfathered in from previous trial protocols — and that a one-size-fits-all approach is not appropriate in clinical trial design.

That group suggested that patients with treated or stable brain metastases for four weeks should not be routinely denied by exclusion criteria, with clearly defined safety exceptions. Their full recommendations were published in the Journal of Clinical Oncology in October 2017.

Of the approximately 300 commercial IND protocols submitted to FDA in 2015, 77 percent excluded known, active or symptomatic brain metastases, while 47 percent allowed treated or stable metastases, they cited. In addition, only 1.7 percent of trials allowed patients with stable HIV.

The researchers found that expanding eligibility in brain metastases can be justified and may accelerate overall clinical development, and recommend that patients with brain metastases should be included in trials where metastases are common in the intended population.
Patient Engagement (continued from page 1)

“IT'S A SIGNIFICANT STEP FORWARD IN THE FDA'S EFFORTS TO BROADEN ITS ENGAGEMENT WITH PATIENTS — AND TO DEEPEN THE INVOLVEMENT OF PATIENTS IN OUR REGULATORY ACTIVITIES.”

—SCOTT GOTTlieB, FDA COMMISSIONER

requests comments from the research industry to help develop strategies to better consider the patient perspective during its evaluations and regulatory approvals. A common theme in the responses included the creation of an external group to inform efforts across review centers, the agency said.

The FDA has since held the inaugural meeting of its Patient Engagement Advisory Committee last fall, focusing on incorporating patient views into clinical trial designs for medical devices. The committee is the agency’s first to be completely staffed by patients, caregivers and advocates.

The committee tested a new meeting format, with agency moderators leading roundtable discussions with attendees from the public. Discussed by the committee were methods to boost clinical trial enrollment and retention, how to keep patients engaged throughout extended follow-ups and how researchers should communicate study results to participants.

“It’s a significant step forward in the FDA’s efforts to broaden its engagement with patients — and to deepen the involvement of patients in our regulatory activities,” said FDA Commissioner Scott Gottlieb at the time.

Center for Devices and Radiological Health (CDRH) Director Jeffrey Shuren called the agency’s previous efforts to seek patient voices woefully limited. A portion of past committee meetings allowed members of the public to speak for only a few minutes at a time, and some only accepted written comments from patients.

In addition, FDA reviewers have begun examining companies’ patient engagement efforts during its 30-day reviews of IDE submissions. According to Owen Faris, director of CDRH’s clinical trials program, reviewers are mainly looking to see whether the right patients will be enrolled in the study; if the patients will be willing and able to adhere to the follow-up visit schedule; and whether study success will equal patient success.

CDRH set a goal to give its entire staff the opportunity to interact directly with patients by the end of 2017. If patients are going to be the ones using the devices, the agency should be taking their perspectives into account, Shuren said.

At December’s FDA/CMS Summit, Shuren reported that 96 percent of CDRH staff had met that goal, and that 80 percent of clinical trials reviewed by the agency had incorporated patient-reported outcomes.

The Patient Engagement Collaborative is only the latest in the FDA’s push for patient input in clinical trials, a measure taken to ensure higher patient recruitment levels, patient adherence to study protocol and fewer protocol amendments to clinical trials.
## Drug & Device Pipeline News

For news on trial results, FDA approvals and drugs in development, Join the LinkedIn Drug Research Updates group!

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<tr>
<th>Company</th>
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<td>VBL Therapeutics</td>
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<td>Rhizen Pharmaceuticals</td>
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Trial Results

Momента Reports Positive Top-Line Phase I Data for M281 in Healthy Volunteers

Momenta Pharmaceuticals reported positive top-line data showing safety, tolerability and proof of mechanism for M281 in a Phase I single ascending dose (SAD) and multiple ascending dose (MAD) study of normal human volunteers. Over the 98-day MAD study, M281 exhibited no serious adverse events, was well-tolerated and decreased circulating IgG levels up to 89% with a mean reduction of 84%. M281 is a fully human anti-neonatal Fc receptor (FcRn) aglycosylated immunoglobulin G (IgG1) monoclonal antibody, engineered to reduce circulating pathogenic IgG antibodies, in excess of that achieved by any current treatments, by completely blocking endogenous IgG recycling via FcRn. Momenta Pharmaceuticals will finalize development strategy and initiate a proof of concept clinical trial in the second half of 2018, pending regulatory feedback. The Phase 1 randomized, double-blind, placebo-controlled study evaluated the safety, tolerability, pharmacokinetics and pharmacodynamics of M281.

Akebia Announces Results of Vadadustat in Anemia Associated with Dialysis-Dependent Chronic Kidney Disease

Akebia Therapeutics announced positive top-line results from its Phase II study of vadadustat in patients with anemia associated with dialysis-dependent chronic kidney disease (DD-CKD) in Japan. The results are consistent with findings from previous studies of vadadustat. Akebia’s partner, Mitsubishi Tanabe Pharma Corporation (MTPC), is conducting a Phase III study of non-dialysis dependent (NDD-CKD) patients in Japan and, based upon the data, is expected to begin Phase III studies in DD-CKD patients in Japan in 2018. The double-blind, placebo-controlled, dose-finding Phase II study was designed to evaluate the efficacy, safety and tolerability of orally-administered vada dustat in Japanese patients with anemia associated with DD-CKD. This 16-week study evaluated 60 patients during a six-week placebo-controlled, fixed-dose period and a 10-week active treatment, dose adjustment and maintenance period. The primary efficacy endpoint was mean hemoglobin change from baseline to week six comparing vadadustat to placebo. Statistically significant improvements in the primary endpoint were observed in the vadadustat groups, 150mg (p=0.0004), 300mg (p<0.0001) and 600mg (p<0.0001), compared to placebo. The data indicate a dose-response for vadadustat.

NxThera Announces Three-Year Outcomes Data of Rezum System for Enlarged Prostate

NxThera announced the three-year outcomes data from the Rezūm II pivotal clinical trial of its minimally invasive Rezūm System, demonstrating significant, effective and durable lower urinary tract symptom (LUTS) relief, improved quality of life and preserved sexual function for men treated for benign prostatic hyperplasia (BPH). The Rezūm II randomized, controlled trial enrolled 197 men from 15 sites in the U.S., and one-, two- and now three-year data from this trial has demonstrated durable symptom relief with preserved sexual function in patients who were treated with the Rezūm System. The seven individual IPSS domains, including urgency and nocturia, indicated significant relief of symptoms at one month, remained significant throughout three years (p<0.0001). Sexual function was preserved in patients treated with the Rezūm System, as measured via the International Index of Erectile Function (IIEF-15) and Male Sexual Health Questionnaire (MSHQ) through three years of follow-up. The ejaculatory bother score (MSHQ-EjD) improved over baseline from 12 to 36 months (p<0.004). No latent related adverse events occurred and no de novo erectile dysfunction was reported. Surgical retreatment rate was 4.4 percent (six out of 135 subjects) over three years of follow-up. Four of these six secondary interventions were related to an untreated median lobe at baseline. Thirty of the patients received treatment to the median lobe or elevated central zone, in addition to treating the lateral lobes; these 30 patients not only demonstrated significant improvements in symptom (IPSS) and urinary flow rates (Qmax), but also demonstrated decreased post-voiding residual (PVR) urine from 24 months to 36 months (p<0.04). Surgical retreatment rate was 4.4 percent (six out of 135 subjects) over three years of follow-up. Four of these six secondary interventions were related to an untreated median lobe at baseline.

Site visibility with every post

Increase your visibility to Sponsors & CROs:
- Generate clinical study leads with online exposure & web ads
- Build awareness of site’s clinical research expertise to industry professionals & patients
- Social Media outreach to 7,000+ professional followers

Customize your page with:
- Images—post photos of your facility and staff
- Videos—link to video presentations

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Upcoming Event Highlights

Conferences

**FEBRUARY 7-8, 2018**
Investigator Initiated Sponsored Research (IISR) 2018
CBI's IISR 2018 is the only annual event dedicated exclusively to helping you and your organization improve your IISR Programs by providing innovative and forward-thinking approaches to support collaborative partnerships, promote proactive contracting, financial planning and integrate best practices in clinical operations for medical affairs excellence in the global expansion of clinical trials.
**Boston, MA**

**FEBRUARY 13-18, 2018**
Scope Summit for Clinical Ops Executives 2018
SCOPE will offer three days of in-depth discussions in 18 different conferences, 3 plenary keynote sessions and interactive breakout discussions focused on advances and innovative solutions in all aspects of clinical trial planning, management and operations.
**Orlando, FL**

**MARCH 6-8, 2018**
FDAnews ICH E6 GCP Interactive Workshops
Get all the ICH E6 (R2) training you need with three days of hands-on workshops aimed at helping you understand and comply with new requirements.
**Raleigh, NC**

**APRIL 4-5, 2018**
Let's Improve Clinical Trials Today!
The forum will discuss how we can bridge people and processes, technology and regulations.
**Oxon Hill, MD**

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**Clinical Research Coordinator**
Company Confidential
Las Vegas, NV

**Assistant Clinical Research Coordinator**
UC Davis Health System
Sacramento, CA

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Boehringer Ingelheim
Ridgefield, CT

**Clinical Trials Manager**
Sterling-Hoffman Life Sciences
Newark, CA

**Clinical Research Study Coordinator**
Alpha Research Associates
Dayton, OH

**Clinical Regulatory Specialist**
Turesol
Phoenixville, PA

**Clinical Research Coordinator**
Massachusetts General Hospital (MGH)
Charlestown, MA

**Manager, Clinical Trials - VICC**
Vanderbilt University Medical Center
Nashville, TN

**Clinical Quality Compliance Lead (GCP)**
Genentech
South San Francisco, CA

**Trial Lead (Manager), Clinical Data Sciences**
Pfizer Inc.
Collegeville, PA

**Microbiology Clinical Trial Scientist**
BioMerieux Inc.
St. Louis, MO

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Academic Programs

Boston College
**Clinical Research Certificate Program**
Chestnut Hill Campus, Newton, MA

Drexel University College of Medicine
**Master's/Certificate Programs in Clinical Research Organization and Management**
Online

University of North Carolina at Wilmington
**MS Clinical Research and Product Development**
Online

[ VIEW ACADEMIC PROGRAM DETAILS ]