Clinical Trial Agreements: Do You Understand All the Important Terms in the Contract?

By Suz Redfearn

Do you understand everything you need to about the clinical trial agreement contracts you sign?

Likely not, as most contain hidden landmines and not everything in them is as simple as you might think, according to Eric Babineaux, legal counsel for Clintrax Global, who spoke during a WCG webinar last week on the meaning of certain words and concepts often seen in clinical trial agreements.

Even establishing the date of a contract is not as straightforward as one might assume, said Babineaux. Most contracts start on the date that both parties sign, but often one of the parties will want to back date the contract, and the other party agrees to go along. For instance, signing parties will make the effective date a date from a few months ago to reflect a protocol amendment in the study, usually for budget reasons. But Babineaux warns against it.

“I would argue that this is inappropriate. Avoid back dating agreements,” he said. “Instead what we should be doing is truthfully reflecting that the agreement is being made with the signing of the agreement, then moving forward with drafting language within the body of that amendment to show that the parties are agreeing that any changes to the budget are going to need to be retroactive back to whatever date that protocol amendment might have occurred.”

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Becoming a Preferred Site: Stay Organized, Consistent and Go Beyond the Basics

By Suz Redfearn

How does a site become irresistible to Sponsors and CROs?

It’s nothing elusive or magical, according to clinical consultants Janet Ellen Holwell and Deborah L. Rosenbaum, who lead an all-day session on the topic at the Association of Clinical Research Professionals (ACRP) annual conference on Friday.

Rather, it’s about consistently executing all the usual site functions at a very high level and with a razor-sharp focus on being organized, following regulations and going above and beyond Sponsor expectations.

Preferred sites execute site operations seamlessly, from instituting and maintaining airtight standard operating procedures (SOPs) to reporting Sponsors that ask sites to perform unethical acts, to recording dates in a way that won’t be confusing to those working on global trials (e.g., 15DEC2015 instead of 12/15/15) to holding onto all study documents until a Sponsor lets the site know it can dispose of them.

What are the common denominators among sites Sponsors really prefer? Said Holwell, sites favored by Sponsors and CROs consistently have the capacity for meeting or exceeding enrollment. They meet deliverables, have strong principal investigator (PI) oversight and regularly demonstrate high quality in all operations.

Those efforts start well before a site makes contact with a Sponsor over a new study, said Holwell, but once contact has been made, it’s a Preferred Site on page 6 »
Novartis Announces Real-Time, Self-Reported Data-Based App for Ophthalmic Trials

Novartis has launched an ophthalmic digital research app that will allow researchers to monitor disease progression through self-reported patient data. The app, FocalView, collects real-time, voluntarily disclosed data from consenting patients, which will allow Sponsors to adapt clinical trial design to patients' routines. The goal is to eliminate some of the most common obstacles to trial participation and increase practical understanding of ophthalmic diseases. The company is planning to test the app in a prospective, non-interventional study to determine its use for evaluating visual function such as acuity and contrast sensitivity. “Because patients with eye diseases are often not as mobile, FocalView has the potential to offer tremendous benefit for the ophthalmic community and for researchers looking to develop better treatments for these patients,” said Mark Bullimore, dean of the Southern California College of Optometry, Marshall B. Ketchum University, who served as medical advisor for the creation of the app.

Boston University Study: Oncology Trials Underrepresent Obese Patients

Obese patients are underrepresented in cancer-related clinical trials, according to new research published in the Annals of Oncology. While cancer types associated with being overweight or obese comprise 40 percent of all U.S. cancer diagnoses, the median proportion of obese participants in 22 clinical trials was only 18 percent. None of these trials specifically listed obesity as a disqualification for involvement in the trials, but 93 percent did not specify whether such patients were eligible to participate. An even greater proportion — 95 percent — of trials did not include information on the proportion of participants who were obese. When unpublished data was taken into account, 41 percent of trials made clear that obese participants were eligible but it was unclear for the remaining 59 percent. This level of underrepresentation, researchers wrote, could potentially make the data produced by the trials less generalizable. "The lack of information regarding enrollment of obese participants stands in sharp contrast with the expanding real-world concern of obesity in cancer and ongoing reflections about improving the assessment drugs’ safety and efficacy in patients who will ultimately receive them," according to the researchers from Boston University’s School of Public Health. “Given the role of obesity in shaping cancer risks and outcomes, our results highlight the critical need to improve the reporting of obesity status information.”

UK Plans to Stick with EU Clinical Trial Regulations Post-Brexit

The UK government aims to stay up-to-date with EU changes for clinical trial procedures amid uncertainties over next March’s implementation of Brexit. The new EU clinical trials regulations were initially meant to be implemented in October 2018, but were delayed by the European Medicines Agency until 2019 at the earliest due to technical difficulties. The agency has called the modernization process its most ambitious IT system requirement in the last decade. The parliament’s proposed Brexit withdrawal agreement and implementation bill allows EU regulations to continue to apply in the UK for the bill’s limited time period. If that bill fails to pass “we will give priority to bringing into UK law, without delay, all relevant parts of the EU regulation that are within the UK’s control” to allow those planning clinical research to do so with certainty, said Baroness Annabel MacNicol Goldie, in remarks before the House of Lords. Two key elements are outside of the UK’s control — the use of a shared central IT portal and the UK’s participation in the single assessment model — as they require a negotiated agreement with the EU about the UK’s involvement post-Brexit, she said. Those negotiations have not started, as the government “[does] not wish to do anything that might disadvantage the negotiating position of the UK” by giving more guarantees. The UK government is committing to “being as aligned with the new EU clinical trials regulation as we possibly can be, subject to the negotiatory aspects,” she said.

FDA Issues Final Guidance on Imaging-Based Clinical Trial Endpoints

Sponsors conducting clinical trials using imaging-based primary endpoints should consider the choice of modality — such as echocardiography or single-photon emission computed tomography — as well as centralized image interpretation and how often image evaluations should be performed, according to final guidance from the FDA. The agency also recommends trial-specific procedures for imaging that extend beyond the imaging performed as part of standard medical care. Sponsors should consider logistical issues when considering imaging modalities for a phase III trial. “Imaging modality upgrades and malfunctions are sometimes unpredictable,” the guidance states. Clinical sites may also experience “unforeseen limitations on the use of the modality or modality-specific imaging drugs and processes, such as the interchange of certain contrast agents that may not affect typical diagnostic imaging but may alter trial-specific quantitative imaging

see Final Guidance on page 3»
Industry Briefs (continued from page 2)

measures. Sponsors must also decide between locating image interpretation at the clinical site or at a central site. Which option is best depends on the role, the susceptibility to bias and the variability of imaging within the trial. A centralized location may be less important for trials where the quantitative measures are widely performed and reported in clinical medicine and the trial design controls for potential interpretive biases. This also affects how soon after acquisition the images should be interpreted; it is normally done immediately for on-site imaging, but for centralized interpretations, Sponsors should determine a turnaround time appropriate to the anticipated trial design. When deciding whether to blind image interpretation to clinical data, Sponsors should factor in the underlying clinical condition and the precedent for using imaging as the trial's primary endpoint.

**Gottlieb Flags Clinical Trial Limitations in Budget Hearing**

In remarks to a Senate appropriations subcommittee on the FDA’s FY2019 budget request, FDA Commissioner Scott Gottlieb discussed the agency’s plans to make use of real-world evidence to supplement what it learns from clinical trials. “No matter the design or size of clinical trials, we can never answer — or anticipate — all the questions we may have before we approve a new product. Thus, we must rely on post-market data tools,” he said. Gottlieb stressed the importance of having a real-time, real-world experience system, as it can give the agency additional ways to expand its knowledge of new product effectiveness. “We can better utilize electronic healthcare data to broaden the indications for use of approved medical products, eventually perhaps conducting much of late stage development in the ‘real world’ making our pre-market development process more efficient,” he said. Gottlieb noted that the budget contains a $100 million proposal to advance the use of real-world experience. It aims to provide efficient, lower cost ways to develop clinical data in order to speed up medical product development and inform patient care. The proposal would give the agency the capability to conduct “near real-time evaluation down to the level of individual electronic health records” for at least 10 million individuals across a variety of healthcare settings, improving the agency’s tools for safety evaluations and possibly reducing the cost of developing medical products, he said. The proposal would allow the agency to link across data sources, such as electronic health records, to evaluate broader sets of endpoints that are currently difficult to access, bringing a “fundamental shift from passive to active device surveillance. These are transformative initiatives that can modernize the foundation of FDA oversight and improve patient safety,” he said.

**FDA Issues ‘Streamlined’ Nonclinical Trial Guidance for Hematologic Disorder Drugs**

The FDA released draft guidance on a “streamlined nonclinical program” for Sponsors of nonclinical studies for development of pharmaceuticals for treatment of patients with debilitating or life-threatening hematologic disorders, saying such nonclinical studies should consider general toxicology, pharmacology and reproductive toxicology. Ahead of any clinical trials for such drugs, Sponsors should assess how the drug potentially affects vital organ functions, including the nervous and respiratory systems, but stand-alone safety pharmacology trials are not necessary, the agency said. The planned dosage and proposed safety monitoring plan for trials should be based on nonclinical data similar to that of anticancer drugs. This typically means study lengths of one month to support first-in-human trials and three months to support phase III trials and marketing applications. “The Sponsor should initiate the three-month repeat-dose studies when a phase II trial starts or as soon as feasible when a pharmaceutical is designated as a breakthrough therapy,” the guidance states. The Sponsor should choose the design of nonclinical studies to approximate the various dosing schedules that might be used in initial clinical trials. Sponsors should assess genotoxicity for small molecule drugs ahead of a first-in-human study, but a full battery is not always necessary. One assay for gene mutation is usually enough to support single-dose clinical studies, the agency said. The starting dose for first-in-human trials should be justified scientifically based on nonclinical data, and Sponsors should determine the starting dose to minimize exposure to subtherapeutic dosages. The agency’s recommendations for assessing reproductive toxicity are similar to those for anticancer drugs in ICH S9. Sponsors may need to conduct fertility and early embryonic development studies, but these can be conducted after approval. The guidance further provides recommendations for timing of submissions of nonclinical study results, noting that the Sponsor can submit study results earlier than the timings listed when a “cause of concern” exists, such as unexpected severe toxicities in phase I clinical data. Read the draft guidance here: www.fdanews.com/04-23-18-Guidance.pdf.

**Most Top Public Funders of Clinical Research Lack Transparency Policies, Says AllTrials**

An audit of the 18 philanthropic and public bodies that spend the most money on clinical research found that the majority do not require researchers to report results and that only half of the funders ask for clinical trials to be registered, according to AllTrials, a clinical research watchdog. The audit, conducted at the University of Oxford, and published in the Journal of the American Medical Association, assessed the funding organizations’ policies on clinical trial transparency under three domains: trial registration, summary results reporting and patient data sharing. Three of them seem to ask for no commitment to transparency from their funded researchers — they don’t mandate any registration, summary result sharing or data sharing. Only two organizations have a requirement that covers all three domains. These are the UK’s Medical Research Council and Germany’s research...
funding organization Deutsche Forschungsgemeinschaft. Sixteen of the audited organizations are public bodies and two are philanthropic organizations (The Wellcome Trust and Bill & Melinda Gates Foundation). Between them, the 18 organizations spend around $40 billion on health research every year (figures from 2013, reference below). In May 2017 the WHO asked non-commercial funders worldwide to sign up to its strong standard on transparency. Six of the 18 organizations included in today’s audit have committed to eventually meeting the WHO standard.

CBER Issues Guidance on Datasets for Vaccine Applications
The FDA’s Center for Biologics Evaluation and Research published guidance on information to include in biologics license application datasets, including data on clinical trial endpoints and adverse events. When clinical disease endpoint efficacy is an objective in the trial, the efficacy data should be primarily reported in the clinical event domain with specific information in the microbiology specimen, vital signs and physical exam domain as necessary, the agency said. Domains to include from clinical trials in dataset submissions include the trial summary, demographics, subject visits, concomitant medications, exposure, disposition, protocol deviations and medical history, as well as physical exam information and laboratory test results, if applicable. Safety data for vaccine clinical trials should include reactogenicity data — a set of adverse events collected within a previously specified time frame, otherwise known as solicited reactions — unsolicited AEs, medically attended AEs and death. Deaths should be reported in the AE domain with supplemental information provided in the death details domain. For laboratory test results, a laboratory safety assessment of clinical chemistry, hematology and urine should be included. If laboratory results are outside of the normal range for a particular assessment, it should be reported with the highest level included. Medically attended adverse events should be noted in the adverse event domain, with additional data reported if necessary in the death details, vital signs, healthcare encounters and/or findings about adverse events domains. New onsets of a chronic disease should be noted in the adverse events domain. Unsolicited adverse events should be represented in the AE domain whether or not they occurred during the pre-specified assessment interval or after. The AE’s clinical details should be represented in the findings about adverse event domain and possibly in the vital signs, concomitant medication, healthcare encounter, procedures and death detail domains. Read the guidance here: www.fdanews.com/04-23-18-Vaccines.pdf.

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Clinical Trial Agreements (continued from page 1)

When in doubt, Babineaux said, it’s better to truthfully represent the date, with both parties agreeing to respect the fact that there may be some rights that go back beyond whenever the contract was actually signed.

Another complicated area, said Babineaux, is indemnification — the clause in which one party agrees to protect the other against potential harms or losses that the other party may incur. This is a big one because if triggered, “it could have a pretty high degree of liability,” Babineaux said.

He advised that those penning contracts be very clear on who exactly is indemnified. He used the example of a Sponsor signing a clinical trial agreement with an institution that has affiliated hospitals. To avoid extending wide indemnification to a whole healthcare system, for example, Sponsors should be specific in the contract about exactly which facilities they will indemnify, naming only those that will touch your study, he said.

And Sponsors and CROs, watch out for the word “gross” when writing the clause stating which types of actions — specifically negligence — will be indemnified and which will be excluded from that protection. Explained Babineaux, gross negligence in the context of a clinical trial is conduct that smacks of intentional wrong doing or implied malice or evil intention or represents an extreme departure from standards of ordinary care. Sometimes one party will negotiate to have the standard for indemnification in a contract raised to gross negligence only, meaning: the Sponsor protects the site from a claim from a third party except when the site has been grossly negligent.

But when that is done, Babineaux explained, the Sponsor or CRO is no longer excluding non-gross negligent acts from the behaviors they will protect, and thus will need to protect an investigator who engages in negligence should a third party file a claim, when that might not be appropriate.

“Gross negligence standard is not applied as consistently across jurisdictions as the negligence standard. It’s a much higher standard than plain negligence which results in conduct that only amounts to negligence but not reaching gross negligence being indemnified.”

—Eric Babineaux, legal counsel,Clintrax Global

“Gross negligence standard is not applied as consistently across jurisdictions as the negligence standard. It’s a much higher standard than plain negligence which results in conduct that only amounts to negligence but not reaching gross negligence being indemnified.”

said Babineaux. “You want to make sure exactly how that will affect your duty to indemnify because you want to avoid increasing your risk liability just through overlooking the addition of a single word.”

Babineaux also pointed out that clinical trial agreements are often signed between CROs and sites, not Sponsors and sites, and this pushes into a new legal area called third-party beneficiary law. Explained Babineaux, the CRO signs an agreement on behalf of the Sponsor, under power of attorney or a letter of authority, and the Sponsor is now a third-party beneficiary to the contract. Under this type of agreement, the Sponsor is able to sue to enforce obligations under the contract even though they are not party to the agreement — but because they are not a party to the agreement, the site can’t sue them.

“The site can’t enforce any obligations against the Sponsor” under this type of agreement, said Babineaux. This can leave a site dangerously vulnerable when it comes to indemnity.

To remedy that, he suggests sites draw up a letter of indemnification to have the Sponsor sign so they can enter into a direct relationship over the matter. “That way, you do have the mechanism to enforce your rights that the Sponsor may owe,” he said.

Clinical trial agreements may seem complex, but if you understand key terms and the ramifications they can have, you’ll be well on your way to protecting yourself during the course of a trial, and clearing the space to focus on the trial without worrying about legal exposure.
Preferred Site  (continued from page 1)

time to go above and beyond. For example, she suggested, sites should create their own recruitment plan for the study, even though that’s not required.

And once the study starts and you’re recruiting, always have an eye on the future, said Holwell. Keep great contact information on each patient so that after the study wraps, no patient is lost to follow up. Check in with subjects regularly during and after the study to ask how they’re doing.

Another way of going above and beyond: organize disease-centric support groups for patients, said Holwell. If you can’t do that, then point them to already existing support groups in the area.

And build a robust database as you work with subjects, she suggested. When screening for a study, ask all people — even those who don’t make it into the study due to exclusion criteria — for permission to call them about future studies.

The session leaders emphasized the importance of robust, well thought out SOPs for site policies, contracting, site procedures and activities, and for specific studies.

Said Rosenbaum, "SOPs bring consistency; they establish who is responsible, they facilitate training, bring compliance and are part of a quality management system."

Rosenbaum advised that sites move toward making all documents standardized, with all information flowing in a consistent manner, but keep it evolving. "The SOP is a living document, so adjust as you go, she added.

And if you’re not electronic, get there as soon as you can, said Rosenbaum.

“Electronic data capture is seen as the holy grail of research,” she said. “Its advantages are real-time data collection and real-time feedback during data entry, edit checks to avoid errors and data-like labs and ePRO are automatically downloaded.”

Noticeable success is also about the PIs and the coordinators staying in close touch, but often that’s not what’s happening. Said Holwell, though the buck stops with the PI, often it’s the coordinators who are doing most of the work, and the two entities can become siloed, even to the point of quality, it’s time to sing your praises to Sponsors and CROs, said Rosenbaum.

“Razzle dazzle them by being prepared and emphasizing your site’s strengths,” she said, adding that Sponsors look favorably on sites that are very responsive, beginning with the feasibility questionnaire.

By ready to showcase metrics from your site highlighting successful audits and recruiting triumphs, and let them know you’re happy to work with a central/commercial IRB.

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Gain the competitive edge

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Sponsors’ heightened awareness of the importance of patient engagement in the design and execution of research studies has led to the discovery of crucial information about participation pain points. The information often reveals huge disconnects in what patients prefer and what they experience. Resolving these disconnects can have a significantly positive impact on patient recruitment.

Many wonder whether the patient centricity movement is actually happening or if it is simply discussed more often. A recent study conducted by the Tufts Center for the Study of Drug Development and the Drug Information Association found that three out of four major pharmaceutical companies have piloted and implemented at least one patient advisory board (PAB), making these activities one of the most commonly implemented patient centricity initiatives.

Patient advisory boards are providing many insights to clinical trial sponsors on patient opinion of clinical trials, before, during and post participation. During a March 27 patient engagement webinar held by The Center for Information and Study on Clinical Research Participation (CISCRP), data was presented showing that prior to participation, the number one reason patients did not want to participate in a clinical research study, after reading the informed consent form, was the number of study visits.

During the trial, the top two reported dislikes were the location of the study center and the chance of getting placebo.

Post-participation, the number one piece of information people want to receive is study results including personal results and overall study results. The CISCRP P&I 2017 survey revealed that, while 91% of patients report that receiving trial results are somewhat or very important, over half of those surveyed (53%) reported that they did not receive any reports or updates post-participation. Future studies can use these insights to design more patient-centric studies and improve patient recruitment.

The number of study visits is a major impediment to agreeing to participate in a study.

According to Deloitte, approximately 70% of prospective clinical trial participants live more than two hours away from the nearest study center. New technology can be used to allow for remote visits — some studies can be completely remote.

Spending on technology because of the cost and because not all patient preferences are the same. Weighing the cost of technology because it is preferred by patients is not an easy sell to stakeholders. While some patients would be more willing to join a clinical research study that supported remote visits, others may prefer to have a face-to-face with the principal investigator. Sites also bring their own perspective. Some sites will readily accept innovative technology while others are more comfortable with “business as usual.”

Many sites struggle with patient recruitment. Many strategies are not measured or tracked. It is true that 80% of trials are delayed, and often due to poor recruitment. It is also true that 48% of sites miss their recruitment targets.

It’s harder to get into trials, and the inclusion and exclusion criteria, as a whole, for clinical research studies have increased 61%, which significantly adds to the screen fail rate. Additionally, 15% to 20% of sites never enroll a single patient and actual enrollment timelines are typically double that of planned timelines.

By listening to patients and hearing the hard truths about their experiences, there is a real opportunity to design clinical trials with the patients in mind and increase recruitment.

Until recently, protocols were often designed without patient burden in mind, so it’s of little wonder that patient recruitment suffers. The patient centricity movement and the growing number of PABs being formed is a sure sign there is a positive shift for the patient experience. By engaging patients and listening to what they say we have an opportunity to make large improvements.

The Pulse on Patient Recruitment  By Ashley Tointon

Cost and Benefits

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For engagement activities resulting in avoiding an amendment and/or an improved patient trial experience, the benefits in cost vastly outweigh the resources spent on engagement.

Source: CTTI, 2017

Ashley Tointon has more than 20 years of patient recruitment and project management experience supporting clinical trials and the pharmaceutical industry. Currently she provides recruitment expertise, strategy and leadership as Principal Consultant of Accelerate Clinical Enrollment LLC. Email tointon@icloud.com or tweet @AshleyTointon.
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Alnylam Reports Results from the APOLLO Phase III Study
Alnylam Pharmaceuticals announced new results from the APOLLO Phase III study of patisiran, an investigational RNAi therapeutic for the treatment of hereditary ATTR (hATTR) amyloidosis. The APOLLO Phase III trial was a randomized, double-blind, placebo-controlled, global study designed to evaluate the efficacy and safety of patisiran in hATTR amyloidosis patients with polyneuropathy. The primary endpoint of the study was the change from baseline in modified Neurologic Impairment Score +7 (mNIS+7) relative to placebo at 18 months. The trial enrolled 225 hATTR amyloidosis patients from 19 countries with 39 genotypes who were randomized 2:1, patisiran:placebo, with patisiran administered at 0.3 mg/kg once every three weeks for 18 months. There were 13 deaths in the APOLLO study; none were considered related to study drug and the frequency of deaths was lower in the patisiran group (4.7 percent) as compared with placebo (7.8 percent). While treatment benefit is observed across all stages of disease, these results support the rationale for early treatment with patisiran to potentially halt or improve neuropathy progression or impairment, respectively.

Paratek Pharmaceuticals Presents Data for Skin Infections Trial
Paratek Pharmaceuticals announced that an analysis of microbiology data from OASIS-2, its second Phase III study of omadacycline in acute skin infections, found that once-daily monotherapy with oral omadacycline is effective in treating frequently isolated pathogens associated with skin infections. The OASIS-2 study was a randomized, double-blind, multi-center study that enrolled 735 adult subjects with moderate to severe ABSSSI at 33 centers in the U.S. Patients received either once-daily, oral omadacycline or twice-daily, oral linezolid for 7 to 14 days. To analyze clinical success per infection type in OASIS-2, the modified intent-to-treat (mITT) population included randomized subjects without a sole Gram-negative pathogen(s) at baseline (n=720). Infection type broke down as follows: 59 percent wound infection; 24 percent cellulitis/erysipelas and 18 percent major abscess. In the pivotal Phase III OASIS-2 study, omadacycline met the FDA-specified primary endpoint of statistical non-inferiority (NI) in the modified intent-to-treat (mITT) population (10 percent NI margin, 95 percent confidence interval) compared to linezolid at the early clinical response (ECR), 48 to 72 hours after the first dose of study drug.

Tarveda Therapeutics Doses First Patient in Phase I/IIa Study
Tarveda Therapeutics announced that it has dosed the first patient in a Phase I/IIa study evaluating PEN-866 in patients with advanced solid tumors. PEN-866 is a miniature drug conjugate that selectively binds to the intracellular target Heat Shock Protein 90 (HSP90) and is linked to SN-38, the active metabolite of irinotecan. The trial is designed as a multi-center, open label, two-part Phase 1b clinical trial of patients with advanced non-small cell lung cancer (NSCLC) and disease progression on prior anti-PD-1/PD-L1 therapy. PEN-866 is designed to activate innate immunity to convert “uninflamed” tumors, which generally do not respond to anti-PD-1/L1 therapy, into “inflamed” tumors, which are responsive to PD-1 inhibition. The trial is designed as a multi-center, open label, two-part Phase 1b study of CMP-001 administered in combination with atezolizumab with and without low-level radiation therapy. Part one of the study will evaluate CMP-001 (5 mg dose) administered subcutaneously (SC) weekly for two weeks and then intratumorally (IT) weekly for three weeks, followed by either SC or IT injection every three weeks. In the second part of the trial, the combination of CMP-001 and atezolizumab therapy will be preceded by low-level radiation therapy to the target lesion.

Checkmate Pharmaceuticals Announces Start of Phase Ib Trial
Checkmate Pharmaceuticals announced that it had initiated treatment with CMP-001 combined with atezolizumab (TECENTRIQ) in a Phase Ib clinical trial of patients with advanced non-small cell lung cancer (NSCLC) and disease progression on prior anti-PD-1/PD-L1 therapy. CMP-001 is designed to activate innate immunity to convert “uninflamed” tumors, which generally do not respond to anti-PD-1/L1 therapy, into “inflamed” tumors, which are responsive to PD-1 inhibition. The trial is designed as a multi-center, open label, two-part Phase 1b study of CMP-001 administered in combination with atezolizumab with and without low-level radiation therapy. Part one of the study will evaluate CMP-001 (5 mg dose) administered subcutaneously (SC) weekly for two weeks and then intratumorally (IT) weekly for three weeks, followed by either SC or IT injection every three weeks. In the second part of the trial, the combination of CMP-001 and atezolizumab therapy will be preceded by low-level radiation therapy to the target lesion.
Research Center Spotlight

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TriWest's mission is to provide a comprehensive set of services to aid in the process of bringing new and effective treatments to the market, through Phase II, III, and IV clinical trials. Their team has a collective history of more than 30 years of experience in a clinical practice as well as clinical research.

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The Center for Rheumatology and Bone Research is a division of Arthritis and Rheumatism Associates, P.C., an eighteen-physician rheumatology practice with five locations.

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In operation since December 2006, The Urology Center of Colorado (TUCC) physician team includes 16 board certified urologists and radiation oncologists. Their mission is excellence in urology.