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Better budgets are needed to ensure survival in competitive CR world

Experts offer tips on improving process

It's a more competitive, tougher clinical research (CR) world out there when it comes to sites keeping track of metrics and creating study budgets. Experts say clinical research organizations (CROs) and sponsors are keeping their own metrics and are returning to high-performing CR sites.

They know which sites are successful at enrolling subjects, how many queries they've received, how many protocol violations they've had, and generally how successful they've been, says **Deena Bernstein,** MHS, director of clinical research at Sheridan Clinical Research in Fort Lauderdale, FL.

CR sites that fail to collect their own data on their performance are at a disadvantage when they write their study budgets.

"If you're keeping these metrics and working more as a partnership with the CRO or sponsor, then you can make changes to the areas where you fell short and improve your processes," Bernstein says.

Sponsors and CROs want to contract with sites that have a track record of success, and one way a CR site can prove this is by keeping its own metrics and writing budgets that accurately predict the site's costs for a particular study.

"We're always looking to have higher-performing, highly-educated research sites that have more experience because it's in the best interest of our company," says **Jim Armbrust,** JD, CRCP, head of Clinical Trial Business Operation Group of MedImmune of Gaithersburg, MD. MedImmune, the biologics business unit of AstraZeneca of London, England, is a sponsor company.

Sponsors understand that they'll get what they pay for, so the cheapest site might not be the best value for a study, Armbrust adds.

"A site that has the experience might cost a little bit more, and that's okay if they're within the fair market value," he says. "It's cheaper for us to pay a little more up front than have to find a whole new site when the cheap site fails."

This is why it's becoming increasingly difficult for new physician researchers to break into clinical trial work, Bernstein notes.

"It's very difficult to land your first trial without clinical trial experience," she says. "So they'll overestimate on the sponsor's feasibility questionnaire because they just want to be awarded their first study."

But it's a huge mistake for an investigator to estimate enrolling 50 patients in three months when that number likely will prove elusive.

"There's nothing worse than getting into a study and finding out you can't enroll subjects, especially since sponsors and CROs are keeping metrics on research sites," Bernstein says.

The key is for research organizations to be proactive, do their due diligence, and perform thorough budget feasibility reviews that rely on past experience and metrics.

Also, there are a number of steps CR sites can take to improve their metrics and budgeting process. Bernstein and Armbrust outline these ideas below:

• **Have separate person/staff handle contracting/budgeting process when possible:** Study investigators need to be involved in interpreting a protocol during the budgeting process, but it's optimal to not have principal investigators do the contracting, Armbrust says.

For large research institutions, there could be an entire contracting group with internal lawyers involved in budget negotiation, he explains.

"The second level is a practice of three or four PIs who do this as a day job," he adds. "They have an accounts payable/receivable group of one or two people who do all the contracting and negotiating with them."

The third level are sites with investigators who have no support system and are doing it by themselves, Armbrust says.

If a CR site operates at the third level, then it's more likely the site will accept a sponsor's budget without thorough analysis and review, leaving little negotiation room.

But at the very least, investigators and CR staff should read the contract and budget carefully because once it's signed and approved, there is little chance it will be amended when the investigator discovers he or she did not charge enough for a particular procedure, Armbrust says.

• **Know your per-procedure actual costs:** "The way we do our budget is by listing items as per procedure or per visit," Armbrust says. "The protocol might require a certain specimen to be obtained, and if the [CR site] doesn't look at that line item and say $40 isn't reasonable for this blood draw, capture and shipment, then there's a problem."

CR sites make the common mistake of overlooking hidden costs, such as the cost of shipping a tissue sample or the cost of storing it at the designated temperature.

"This is an area that commonly is misunderstood or underestimated in a fair market value,"

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EDITORIAL QUESTIONS

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Armbrust explains. "They may have a blood draw that we pay $40 to take and ship back, but if it costs them $100 at the end of the day, they're losing money."

Investigators who sign off on these budget items without thoroughly reading and understanding the protocol's demands will run into problems that could result in the site's failure in completing the study.

• **Create bar charts with site's metrics:** "We have bar charts, called visual displays, that we create and share with sites, including information on when the study starts, what our planned enrollment is for the entire length of the study, and what is our actual enrollment," Bernstein says. "We update these charts every month."

Each site has a site-specific chart that is available for all to see in the office.

By keeping metrics visible, CR sites can emphasize what's important, such as meeting enrollment goals.

"This helps keep everyone aware of what goes on at a site," Bernstein says.

• **Find industry benchmarks:** Even the smallest of CR sites will greatly improve their budgeting process if they invest in software or data that provides industry benchmark costs, Armbrust suggests.

"What they can assume is the sponsor will give them a range within the fair market value for their jurisdiction," he adds.

With industry benchmark data, CR sites can at least accurately pinpoint what particular protocol procedures would cost the average trial site in their region, even if they cannot identify their own site-specific costs. This means they would be less likely to greatly underestimate or over-estimate costs.

• **Focus on key goals, such as meeting target enrollment:** "Most budgets are negotiable, but our main concern is whether we can enroll and meet our target enrollment," Bernstein says. "This whole process is about making a commitment to a protocol, and you have to do a thorough job with details about every particular patient visit."

A clinical research team needs to dissect the protocol and analyze it for enrollment issues and obstacles. *(See story on creating a study feasibility tool, p. 16.)*

"The worst thing that could happen is that you accept a study and can't really enroll because some small nuance in the protocol prevents you from meeting that enrollment," Bernstein says.

• **If a site determines a procedure will cost more, justify that request in writing:** CR sites can return to sponsors and ask for more money in the budget being negotiated, but they'll need to defend their request in writing, Armbrust says.

"We have, as a sponsor, the duty to stay within fair market value, so if one site next to you is paid $100 and you come back and say it will cost $1,000 for that procedure, then you'll have to give me substantial information about why your costs are much more than the costs of the site next you," he explains.

The best way to handle this is for the site to be transparent and tell the sponsor what its actual cost is for a particular procedure.

In writing, say, "We are certifying that those costs are true and correct costs," Armbrust says.

Sponsors need this in written, formal language so that if the sponsor experiences a financial audit by regulators, then the sponsor has the written document showing why a particular site was paid more than other CR sites, he adds.

• **Show sponsors what your institution's overhead costs are:** Different research institutions can have a wide variety of overhead costs, ranging to high double digits.

"The most common question I hear is 'How do we deal with our own institution's overhead?'" Armbrust says.

Many large institutions have an overhead that is mandated to each study team running a trial, and this cost has to be tacked onto the per subject budget cost.

Sponsors will want to know what the institution's overhead costs are and see information justifying these costs in policies and procedures.

"We may ask their legal staff to put on institutional paper the reason why they have these overhead costs and give us explanations of why these are reasonable," Armbrust says. "We have to have the paper trail to give us defensibility."

But if it's an absurd amount of money, the sponsor likely will walk away and find a less costly site.

Sites that perform their own metrics and can show during the budgeting process why their costs are justified ultimately will be the more successful research sites in both obtaining studies and executing them, Bernstein says.

"Our business had definitely improved over the past year, and we're definitely getting more of an influx of studies," she adds. "We have a lot of repeat business from sponsors we've been doing business with for years." ■

Develop a study feasibility process that makes budgeting a cinch

Create a feasibility tool

Clinical trial sites can improve their budgeting process by developing a good study feasibility process. Sites might use a feasibility tool to help prevent the site from underestimating a clinical trial site's costs for any particular protocol.

Feasibility tools can help a clinical research (CR) site determine if a study should be given a green light, says **Deena Bernstein**, MHS, director of clinical research at Sheridan Clinical Research in Fort Lauderdale, FL.

"We developed a feasibility tool from scratch," Bernstein says. "We sat down and looked at all that was important when accepting a protocol, and then we developed a form initiated by a study coordinator and principal investigator."

Here are some key features of the feasibility tool and process:

• **Overview:** The first step is a brief overview that might be accomplished within 48 hours.

"It's a quick assessment that should take the study coordinator and principal investigator (PI) half an hour to do," Bernstein says. "They look at the study objectives, patient populations, inclusion/exclusion criteria, and protocol-related procedures."

After reviewing all the criteria, the PI and study coordinator need to decide whether they should continue pursuing the protocol.

If the answer is "No," then the investigator should state the reason why the study wouldn't work for the site. If the PI and study coordinator decide the study should be pursued, they should send their recommendation to the central office or next level.

• **Dissect protocol:** Once everyone agrees to pursue a protocol, the project manager or another designated person will notify the sponsor and move forward to the next step of dissecting the protocol.

Now it's time to do a more complete review of the protocol, assessing it for details about the study population time frame, special pre-treatment procedures, post-treatment procedures, expected adverse events, special equipment needed, outside vendors used, and other items in the contract, Bernstein says.

It's important to note all procedures that must be done for the study, but which are not performed in clinical care setting, she adds.

"Also, be accurate on the compliance aspect," Bernstein advises. "Studies can be quite complicated, and we have to make sure we're billing patients' insurance correctly."

A budget should list procedures that are standard of care and those that are not standard of care.

"Then, we really want to know what the physician and study team believe they can enroll per month and per year in a study," she says. "If there are some problems and issues they've identified in the protocol, we want to know about those so we can go back to the sponsor early on and address those concerns with possible amendments."

• **Ask for projections from study team:** "We want the study team to give us projections," Bernstein says. "We have a feasibility tool in place."

If the team's projections prove inaccurate, the research site can find out what went wrong and try to correct the mistake for future study feasibility processes.

Sometimes a site's past experience with enrolling a particular study population fails to predict future experience because of an unpredictable change in circumstances.

For example, an ob/gyn site might agree to do a study involving amniocentesis. Such studies had good enrollment trends in the past, but this study team failed to anticipate a change in climate for the procedure. Pregnant women were less interested in amniocentesis now than they were previously, so the study's enrollment might flounder, Bernstein says.

The same study might have great enrollment at a maternal-fetal medicine office where women at high risk for pregnancy problems are seen. So when this mistake is discovered, it might be possible to find an alternative way to achieve the necessary enrollment.

But the key point is the study team made an error by not looking at the ob/gyn office's data to determine that amniocentesis is performed less often now than previously.

• **Create a recruitment plan:** "It's the study team's responsibility to create a recruitment plan," Bernstein says. "Once they've determined the plan, the project manager will meet with the study team and go over the details."

The recruitment plan includes the advertising campaign and might address all parties involved in executing the plan, including vendors, sponsors,

and the IRB.

"The goal is to be up and ready at the study's starting date," she says. "You don't want to wait, because enrollment is so competitive these days and you want everything ready to go at the site initiation."

• **Do a post-mortem:** After a study is completed, it's a good idea to look at what worked and what did not work well.

If a study failed to do as well as projected, then ask these questions:

— Why didn't it do well?

— Was there something we did to prevent it from doing well?

— If so, what are we going to do to change the process?

If the post-study analysis shows that there was no way of anticipating this particular problem, then the CR site will need to keep in mind that this is the type of protocol that likely will not work for this site.

"This is something you want to realize early in the feasibility process; you want to catch it upstream," Bernstein says.

"If you don't have a great study population, then you won't make it, because the patients aren't there," she adds. "So don't accept a study if you can't enroll; this is greatly appreciated by sponsors, and they'll remember you in the future." ■

Strike fine balance when placing ads to recruit research subjects

Keep in mind what IRB will say

Research investigators need to find a balance between giving enough information about potential subjects in study advertisements to giving too little information and being inundated with unnecessary calls.

Subject recruitment marketing is the first stage in the subject consent process, so investigators should pay close attention to how this is handled.

"If you don't find that balance of giving enough information in the ad then you'll have unqualified people call, and sites will be inundated," says **Matt Baker**, CIP, founder and chief executive officer of Compass IRB of Mesa, AZ.

When sites give too little information on their recruitment materials, but include just the dollar amount subjects will be compensated, they run the risk of soliciting calls based solely on the subject fee offered.

"We see ads that say, 'Call Dr. So-and-So and earn up to $2,500,' and that's all they say," Baker notes.

For example, an ad might read: "Hey … are you a healthy volunteer? Call this number and you may earn up to $2,500."

The study might require subjects to have six overnight visits, multiple blood draws and take an investigational drug, but potential subjects would not learn this from the ad, and that can be a mistake, he adds.

"You don't want people to respond to advertisements for the wrong reason or after they've seen way too little information," he says. "There should be enough information in the ad to find the study volunteers you are looking for without enticing them for the wrong reason."

Some research ethics experts have suggested that research sites should not include dollar amounts in their recruitment advertising because it could be too much of an inducement.

The regulations do not prohibit this practice, but IRBs might limit or change the study recruitment advertising, making decisions about whether or not the dollar amount should be included, Baker says.

IRBs might decide that recruitment ads should not include dollar figures unless they specify all the activities subjects will need to do to complete the study and earn the compensation.

Baker offers this suggestion for a way to write a recruitment ad without mentioning a specific dollar amount of subject compensation: "If you are selected for this study, you will receive compensation for your time and travel."

Compass IRB usually asks investigators to include information in their recruitment advertising about how long the study subject will be participating in the study and whether there are requirements of overnight observation stays or other burdensome procedures or requirements, Baker says.

Investigators sometimes argue that their recruitment ads will appear in a banner ad on Facebook or other online social media, so they don't have room to provide details about the study. An online banner advertisement might be one inch by two inches, leaving little room for text.

Investigators realize they have maybe 10 seconds of that flashing banner ad to attract potential

subjects, so they want to make this one or two-line space as appealing as possible.

"Our question is 'Are you trying to lure people in with the dollar amount and hoping they'll be okay with the details of the study after the fact?'" Baker says.

However, there are other debatable issues raised when investigators use online advertising or place study information on a social media site.

Using social media for recruitment advertising is not against the regulations, but it starts to open some ethical issues, Baker notes.

"Also, how do you ethically use social media advertising?" he adds. "The board has concerns about research sites opening a new page on Facebook or accounts on MySpace to tell people about a study."

An IRB's questions about this type of study recruitment marketing might include these:

- What are the ethical issues raised by this type of advertising?
- Is there someone from the investigator site watching the post?
- Is there someone who has to accept the post or who can reject the comment if it's inappropriate?
- Can someone host the discussion board?
- Could the research site limit the ability for people to provide feedback?

"If sites don't have that level of moderation, it opens the door to problems," Baker says. "A disgruntled subject or a well-meaning subject might accidentally misrepresent the study and give a false impression."

There might be family members of research subjects who place inappropriate comments about the study on their Facebook page. Or someone else might say they were on the study drug and found that it cured their disease — even though they were in a placebo-controlled study and subjects have no way of knowing whether or not they received the study drug or a placebo, he explains.

"Our concern would be if there are ongoing discussions about studies," Baker says. "There are websites out there dedicated to professional research subjects, and this might offer them an opportunity to debate whether this site is better than that site."

When research sites use social media for recruitment marketing without a moderator, it opens up ethical issues that might lead to lengthy IRB debates.

Obviously, IRBs have no control over what individuals might put on their social media pages, unless it reaches the point of requiring legal action. But IRBs will want to make certain that research sites are not using social media in a way that opens the door to irresponsible posts.

IRBs typically pay close attention to how research sites advertise and market study recruitment because it is the research site's first interaction with the subject, Baker says.

"We want sites and investigators to realize this truly is the beginning of the consent process, and we want potential subjects to have a good first impression," he adds. ■

QI office runs more efficiently with good data collection

Consistency is the key

A research institution's quality improvement program can greatly improve its processes and quality by following a few principles: standardize activities and collect and track accurate, comprehensive data.

A QI program's database is the hub of its information, and it's important to have policies and processes in place that describe how data are collected and organized, says **Sarah White**, MPH, CIP, assistant director of the human research quality improvement program at Partners Healthcare in Boston, MA.

The Partners Healthcare QI program office serves as a regulatory support and education group for the Partners research community and among other services often provides onsite audits at the request of investigators and clinical trial sites. The electronic, online service request form, which collects demographic information of the person making the request and other visit details, makes this a much easier task than if it were handled with telephone calls or letters. A standard list of observations is an efficient way to document and track what was observed during the audit.

As a whole, the database can be queried to provide metrics to track down service demand and to identify trends of noncompliance. *(See story on identifying trends, p. 20.)*

"We've standardized our program activities to accurately track services," White adds. "We've also spent a lot of time thinking about how we

are communicating this information to different groups within Partners."

Since the QI program standardized activities and observations and developed a way to automatically generate the reports, the staff time spent on drafting a QI report has greatly decreased.

"We went from maybe two or three hours in writing the report to 30 minutes," White says. "It's freed up a lot of time, which allows us to provide more education and service to the clinical sites."

The next step would be to make the process even more efficient by having QI specialists take laptops to site reviews and key in information as they go through the review. When this happens, it would be possible to generate a report almost immediately, White notes.

QI reviewers have to provide some personal input in the reports, but most of the information is generated from the data collection fields, she adds.

Making data collection improvements such as these are key to building a more efficient and useful database. A QI program can collect multiple gigabytes of data, but if it's not structured in a way that makes it efficient or logical for communicating for others, then it's not very useful.

Some suggestions for questions to ask when structuring data collection are as follows:

- What information does the research office need to know in detail?
- How can information be grouped and summarized (i.e., in education and/or noncompliance)?
- Which categories of clients receive services from the QI office?
- How could the necessary information be standardized (i.e., standardizing the investigator's name and the way the name is tracked by making the user insert a last name and first name separately)?

"We also have a standardized way of tracking department and funding source information," White says. "We have made those categories consistent with other groups in the institution, such as the IRB, so if we want to collaborate and pull metrics together, we have similar lists."

Once a site agrees on the main features of standardizing data, then the electronic data collection tool can be modified to make it easier to collect what is necessary.

For instance, a site might want a drop-down list for selecting dates on a calendar. This could reduce the number of errors made by staff inputting the wrong month or year.

"Dates were one of our biggest problems, which is why we use the drop-down calendar," White says. "Doing this ensures a consistent date entry, so when we want to run metrics between certain dates, the data are clean and queried efficiently."

Using menus of options for data input creates a more consistent data-tracking process.

"When you're tracking information you find that it's very easy for four different people to enter information in four different ways," White explains. "The goal is to get the information in consistently, in order to get it out efficiently."

So when a QI program is called by a department or institution to summarize data on a particular item, this can be done quickly and accurately.

"We've spent a lot of time in the last 18 months creating a very robust database to collect information," White notes. "It starts with an online service request form that the online community can fill out with the standard fields for last name, first name, service they wish us to provide, institution's name, department's name, funding source, and years involved in research."

When the information is entered, it's automatically uploaded in the institution's web-based database, and it's available for QI staff to review.

"Then we communicate with the site to schedule a QI visit and enter visit details into the system," White says.

The next step is to standardize the information observed at the site visit.

QI specialists compare a site's CT activities with requirements in federal regulations, institutional policies, and good clinical practice.

"If they are doing something not in compliance with those things, we make an observation, which generally is standardized in some way so we can track them," White explains. "We've taken a lot of time to build an observation index that has broad observations categorized in different areas of noncompliance and documentation."

When QI specialists make the observation, they use a drop-down list to find the correct category and observations, and the observation is logged into the database.

The Partners QI office has about 100 different observations and eight different categories.

"Those are all tracked and linked to a specific regulatory citation and to a suggested corrective action," White says. "That's our greatest efficiency — that our database can generate a report for them."

Despite a standard observation index, each report generally requires some additional information specific to the site, such as examples of the observations of noncompliance, White notes.

However, this is a small piece compared with the entire report, she adds.

It takes some planning, time and work to build an observations catalog. Each time a QI reviewer makes an observation that is novel, it is considered for addition to the index.

But there are rewards for this level of planning and detail. For instance, a QI program can check monthly for trends in the observations reported. Also, QI programs can scale the observations according to the seriousness of the noncompliance.

"We scale observations based on an internal scale of one to three," White says. "The scale is a way we communicate internally: if you have 15 different observations, which are the critical ones?"

The scale is flexible based on the context.

For instance, during an onsite audit a QI specialist could observe that adverse event tracking and assessment is inadequate. In discussion with the site, the QI specialist could learn that adverse events are in fact tracked and assessed; however, documentation is poor. Or they could learn that, in fact, adverse events are not tracked and assessed on a routine basis, which would be a major cause of concern.

In the former case, the observation would be scaled to 1; the latter, to 3.

CT investigators have responded positively to the electronic data collection and reports, partly because the QI program now can identify more easily their noncompliance trends and correct them before they're audited by external regulators.

"They can have an internal group look at their data in an objective way and tell them if they're doing anything wrong," White says. "In addition, we are able to provide research management with information to understand where noncompliance is occurring and if there are educational gaps and unmet needs." ■

Electronic databases can find trends more easily

Identify, track, make process changes

A well-conceived electronic database can make it possible for a quality improvement (QI) department to quickly identify and act on noncompliance trends.

Using a web-based electronic database system, the human research quality improvement program at Partners Healthcare of Boston, MA, has built a quality improvement review process that works quickly, efficiently, and is useful for finding trends.

"We can give investigators detailed data for self-directed improvements," says **Sarah White,** MPH, CIP, assistant director of the quality improvement (QI) program at Partners Healthcare.

QI specialists can show a group of investigators aggregate data on the most frequent noncompliance observations. Then investigators can compare this information with their own site's activities.

Also, the QI program can share trends of noncompliance with the institution's IRB office that can use it to look for ways the office's own policies and procedures could be restructured to reduce research site noncompliance.

For instance, the QI office might identify a trend of record-keeping problems that would generally not be reported to an IRB as noncompliance, but still must be corrected, White says.

"The IRB has guidance for those, and we'll look at the guidance to see if we need to define our audience a little better or push for more education at research sites," she adds.

One common trend is incomplete or inadequate study management practices. An example of this is when an investigator's curriculum vitae (CV), evidence of training, and qualification are not documented when required, White says.

"This is an administrative issue, but it reflects on the study's management success," she explains. "These types of observations generally are not reported to the IRB, but it's an issue that could lead to regulatory noncompliance in the event that someone is working on a study when they lack the necessary training and qualifications."

When QI specialists come across this type of incomplete paperwork, they will advise a site to improve their documentation of staff qualifications. If they see an observation frequently enough, they might ask the IRB to further clarify its guidance to ensure that investigators and study staff understand their responsibilities in documentation, she adds.

As a QI office reviews its database for trends, here are some questions that should be asked:

- Which sites are involved in this trend?
- Does the observation involve minimal risk studies or principal investigator-initiated studies?
- Do they involve drug or device studies?
- Who are the CR professionals having this problem and how can the QI office correct it?
- Would it help to send out email education to all CR sites?

• Should an educational workshop be created for specific research professionals or departments?

• Which systematic changes might be necessary?

• Which institutional policies could be changed to address this trend?

A standardized database makes it both possible and fairly straightforward to answer these sorts of questions about trends.

Most QI programs are moving in the direction of collecting metrics, identifying trends, and standardizing their data collection process, White says.

"The whole idea of having a standardized database is something most QI programs are thinking about now," she adds. ■

Expert offers negotiation strategies sites can use

Asherman's model is basis

Research sites often focus on finding any studies that might fit their patient populations and let sponsors or clinical research organizations (CROs) take the lead in negotiations. But this could be a mistake. Sites could be missing opportunities to build better site-sponsor-CRO relationships, all because they lack optimal negotiation and trust-building skills.

If they were to focus on improving negotiation skills, this would have a positive impact on their communication and contracts with CROs and sponsors.

The key is to approach negotiation with a basis in building and maintaining a mutually-trusting relationship in which each party tries to understand and meet the other party's needs whenever possible, says **Barry Sagotsky**, MBA, owner of Magnolia Lane Consulting in Princeton, NJ, and a partner with Asherman Associates in New York, NY. Sagotsky has spoken about negotiation techniques at national conferences and bases his strategies on the model developed by Ira and Sandy Asherman, principals of Asherman Associates, who have written numerous articles and edited books about the negotiation process.

Sagotsky offers these suggestions for how to improve negotiation skills and strategies:

• **Discuss all of your issues:** "Many people don't take the time to discuss all the issues on someone's mind," Sagotsky says. "They focus on the biggest issue and then start jumping in and working on that one, overlooking a lot of opportunities for trade-offs and concessions later on."

Also, clinical trial site investigators and negotiators should encourage sponsors and CROs to discuss all of their issues.

"You can explore and understand the other party's needs, interests, and objections without agreeing with them," Sagotsky says. "When you do try to understand their needs, you have a much better chance of having them interested in understanding your needs and motivations."

This discussion of each party's needs and interests answers the common question of "What if others are not playing the same way I am?"

Negotiators who spend time figuring out the other party's interests are more likely to figure out what is the common ground between them, Sagotsky says.

"This can lead to a compromise or collaboration," he adds.

For example, a CRO could push hard on price during negotiations with a research site and win this point. But if the CRO hasn't learned more about the research site's resource and economic pressures, then the price it won might be at the expense of service delivery, Sagotsky explains.

"The other party is going to try to deliver a service that is in line with what he is being paid," he adds.

• **Negotiate X based on delivery of Y:** From a CRO's or sponsor's perspective, it can be beneficial to negotiate a specific price that is based on the successful study enrollment at specific time points.

From the trial site's perspective, this type of negotiation might satisfy the site's need to have control over certain aspects of the study enrollment. For instance, the negotiation might go as follows: "We'll guarantee a certain level of enrollment if we can control the screening at the site, which will cost you extra," Sagotsky suggests.

When research sites are negotiating on the issue of study enrollment they are more likely to meet their objectives if they understand and address the sponsor/CRO's needs and interests, he adds. *(See story on negotiation steps, p. 22.)*

• **Ask for participation in protocol development/revisions:** A fairly common issue with investigators involves inclusion/exclusion criteria.

"People at sites want to be part of that discussion of how to appropriately have inclusion/exclusion criteria relative to the statistical results the company needs or the number of randomized subjects that the site or CRO need to finish the study on time or ahead of time," Sagotsky says.

Both sponsors and investigators want to make sure the right people are enrolled in a study and that subjects will stay enrolled until the study is completed. But the investigator might have a better idea of how certain inclusion criteria or procedure requirements could negatively impact that enrollment and retention.

"If these factors are not discussed or thought through when the protocol is designed, then it could have implications for enrollment and future negotiations," Sagotsky says. "An investigator might say, 'Yes, I have the population, but they won't put up with this procedure because ...'"

An investigator might be able to say during negotiations, "You can get the results you need to prove your claim with a different set of inclusion/exclusion criteria."

Most studies' inclusion/exclusion criteria can be up for negotiation, including both medical and clinical operations. And it's an area that should be brought up early in negotiations rather than waiting until the study begins and problems crop up, Sagotsky says.

"If one group says, 'This is my responsibility, and I don't need anyone else's input on it, then it's a systematic piece that makes negotiation tougher,'" he adds.

• **Structure your site's systems to make negotiations easier:** "You may have overriding organizational and structural systems and issues that make negotiation easier or more difficult," Sagotsky says.

For instance, a site that has a cross-functional team is in a good position to be flexible when studies call for labor-intensive procedures. The cross-functional team would make it easier for the site to handle weekend study visits if needed and give that particular site a bargaining chip that could be used for other concessions.

"This is the kind of thinking that happens with a high-performing team where people focus on the organization and results of the work rather than on the pieces of the organization," Sagotsky says.

Research sites that have roles and responsibilities put into silos, divided between medical and operations, have less negotiation flexibility.

"There is less communication and trust in organizations with silos," Sagotsky says.

• **Make contingencies during negotiations:** It pays to know your own, and the other party's, top priorities and objectives. With this information, a clinical trial site can add concessions with contingencies to negotiations.

For example, a CT site negotiator could say, "I'll give you this if you give me that," Sagotsky says.

Also, contingencies can be given expiration points.

"Someone might say, 'If you refuse my offer of a concession then my concession is no longer on the table,'" Sagotsky says. "Anyone has the power to do that."

Here's an example of how this might play out:

One negotiator says, "If I give you this dollar amount, will you give me this report at the times I specify?"

The other party says that he cannot give the information at those particular dates.

"No? Then I'm no longer offering that dollar amount. But if I give you this particular information at these times, will you be able to give me the reports at the times that I need them?" The first negotiator replies. "I still need the reports on time."

The key is to come back to your chief objectives, adjusting offered contingencies to get there. ■

Here are some steps to follow in negotiations

Plan, set climate, clarify

Clinical trial site investigators and others involved in contract negotiations can improve their negotiation techniques by following six simple steps, an expert says.

Barry Sagotsky, MBA, owner of Magnolia Lane Consulting of Princeton, NJ, and a partner with Asherman Associates in New York, NY, outlines key strategies to negotiation success, as follows:

1. Plan your negotiation strategy.

As part of planning, determine your own important issues and whether you have data to support your point of view. Also anticipate how the other party will react and what they'll want from the meeting. It's also a good idea to know what your ideal outcome is versus what you are willing to accept.

"People don't prepare and often are too anxious to get into it because they think they don't have time to negotiate," Sagotsky says. "Why shouldn't you spend an extra half hour getting it right when you're involved in the negotiations rather than wait to fix it later after the negotiations are done?"

2. Set the right climate.

"This takes an extra minute or two, but its objective is to reduce anxiety so the other party can hear what you are saying and react appropriately," Sagotsky says.

"A lot of people want to just start in the negotiations, saying, 'Let's get to it,'" he adds. "But that's not something that calms down the other party; some people are less likely to talk then and have less trust."

3. Clarify the issues.

This step outlines the reason for the meeting and establishes the issues of both parties.

Negotiators at this step will ask good questions and follow-up points so they'll understand what the other party is interested in achieving.

"The main job of a negotiator is to find out why the other party thinks they're right," Sagotsky says. "It's a truth that each party is right in their own mind or thinks they're right — no one comes to negotiations knowing they're wrong."

So the issue identification step helps a negotiator find out why the other party believes what they do.

"This is the most overlooked piece of the negotiation process," Sagotsky says.

"People tend to go to talking about price, talking about why the price may be too high," he adds. "But if you talk about the price and delivery and quality and length of relationship and those sorts of things that both parties might be interested in, then you will have more concessions and compromise."

4. Make room for negotiating give and take.

At this point in the negotiations, a person might discuss the issues that were identified and ask for input on how each side can meet these objectives.

"A negotiator might ask, 'What are we going to do about getting you what you need and getting me what I need?'" Sagotsky says. "This is where continuing to listen and ask questions is important, and it's a way to also deepen the relationship and trust."

When this is not done well, the relationship can become worse.

"How you handle give-and-take will have an impact on your relationship the next time you meet," Sagotsky says. "We're consulting and not bargaining or pressuring to have a winner or loser; it should be a win-win negotiation."

1. Solve the problem.

At this point, negotiators should determine what needs to be done to reach a settlement.

"The first part is working through the issues you've identified during bargaining and going back and forth," Sagotsky says. "You make concessions, bargain, and now you come to a settlement."

Negotiators can solve the problem by summarizing the agreement and rechecking to make sure everyone understands what is being agreed to before finalizing the settlement, he adds.

2. Review the negotiation process and reach a settlement.

Clinical trial site negotiators should see a review process as their last step.

"How did the negotiations go?" Sagotsky says. "Look at the planning and preparation and determine what worked and what didn't."

Assuming a study site will meet again with the same sponsor or clinical research organization, the review process will help inform later negotiations.

The review also will provide clues as to how a site can improve its relationship with the sponsoring organization. ■

CNE/CME OBJECTIVES / INSTRUCTIONS

The CNE/CME objectives for *Clinical Trials Administrator* are to help physicians and nurses be able to:

- review pertinent regulatory mandates;
- develop practical clinical trial oversight strategies;
- review best practices shared by facilities that successfully conduct clinical trials.

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a letter of credit. When your evaluation is received, a letter of credit will be mailed to you.

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CNE/CME QUESTIONS

5. Which of the following is a good step to take when the goal is to improve the contracting/budgeting process?
A. Have a separate staff person handle budgeting and contracting
B. Determine your per-procedure actual costs
C. Find industry benchmarks
D. All of the above

6. Which of the following is not a question an IRB might ask an investigator about the clinical trial site's planned study recruitment marketing?
A. What are the ethical issues raised by this type of advertising?
B. If advertising is online and involves a virtual forum, is there someone from the investigator site watching the post?
C. How much do you plan to pay for the advertising?
D. Could the research site limit the ability for people to provide feedback online?

7. Research quality improvement (QI) programs need to build more efficient and useful databases. Which of the following is a good question to ask when structuring data collection?
A. What information does the research office need to know in detail?
B. How can information be grouped and summarized (i.e., in education and/or noncompliance)?
C. Which categories of clients receive services from the QI office?
D. All of the above

8. Why do good negotiators spend time figuring out the other party's interests?
A. Because this gives them a wedge to use when pursuing their own main objectives
B. Because they are more likely to figure out what is the common ground between them and this can lead to a compromise or collaboration
C. Because this is information that might be useful when later deciding which entities the negotiator would like to contract with in the future
D. None of the above

Answers: 5. D; 6. C; 7. D; 8. B