The CenterWatch Monthly

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Multigenerational Workforce Requires Customized Approach to Team Building

By James Miessler

*Cohesive, high-performance teams are the backbone of any successful clinical research program. In this Q&A article, **Carmin Gade**, chief marketing officer for WCG, shares insights on developing strong teams, fostering healthy and open communication, and understanding today's clinical research workforce.*

CWM: How would you describe today's clinical research workforce, accounting for generational, cultural and other differences?

CG: Today's clinical research workforce is remarkably diverse, comprised of multiple generations and a variety of cultural backgrounds, each bringing unique experiences to the table. Baby boomers contribute a wealth of knowledge and experience, Gen Xers offer a blend of traditional and modern approaches, millennials are known for their tech-savviness and collaborative mindset, and Gen Zers bring fresh perspectives and digital fluency.

This diversity fuels creativity and innovation, although it also necessitates thoughtful management to harmonizethe different working styles and expectations inherent to such a varied group. With many companies now working remotely, this diversity extends to work environments and schedules, requiring even greater attention to communication and collaboration strategies.

CWM: What is key to assembling, managing and supporting a multigenerational team in clinical research today?

CG: It's critical that you set clear expectations and understand what motivates individuals as you develop processes and programs aimed to optimize performance and effectively engage team members. Suc-

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Warning Letter Walkthrough: Making Monitoring, Site Activation Top Priorities

By James Miessler

A recent FDA Warning Letter illustrates to sponsors the importance of properly managing monitoring responsibilities and having a thorough site activation process. In this article, we'll examine the letter received by the sponsor of a multisite trial of a device for preventing recurrent ischemic stroke and discuss how problems could have been avoided in the first place.

The letter, which was sent to Anthony Nobles, chairman and CEO of Nobles Medical Technology II, a vascular suturing devicemaker, details four serious violations caught by the FDA during its October 2023 inspection.

Warning Letters are issued by the FDA to sponsors when concerning conditions are observed during GCP inspections. While they don't necessarily lock the agency into taking enforcement action, Warning Letters are serious and provide the sponsor and investigator(s) with the opportunity to make moves to correct and prevent the issues at hand. Failure to do so can result in legal and regulatory action and, theoretically, civil monetary fines, although the agency has been criticized for being weak on enforcement in this area.

Nobles' first citation, failure to ensure proper monitoring and IRB review/approval, centers on faulty monitoring and investigators not receiving key information from the sponsor for properly running the trial, including signed protocols, investigator brochures and labeling.

For example, the FDA found the sponsor did not have a written monitoring plan or procedures, case report forms (CRF) had late investigator signoffs, and site monitor-

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Choosing the Right Path to Professional Advancement

Successful professional development in clinical research is not measured by the specific path taken, but by two variables: the journey and the outcome. In this contributed piece, ***Elizabeth Weeks-Rowe****, accomplished CRA, trainer and author, expands on this way of thinking with perspective on the many career course possibilities in clinical research.*

There is no templated course the ambitious must pursue to achieve their goals in clinical research; their options are endless and can either be linear or oblique to reach their professional destination. The key is to have the insight to choose the path suitable to the circumstance.

The journey is critical as it forces theory to practice with each experience. The pace may be slow and practical, or rapid and risky, but either choice crafts the essential lessons required to propel individual professional development to the desired outcome.

The linear path has a planned trajectory from point A to point B, such as a study coordinator moving to a CRA position, or a CRA moving to a CRA manager or clinical trials manager position. This path is carefully plotted, with the individual never losing sight of the goal on the proverbial horizon line. Several successful years are spent in each respective role to gain the knowledge sufficient for career progression. This journey cultivates confidence and emotional maturity with methodical measure.

The oblique, curved course invokes risk. Individuals who traverse this path face rugged terrain, scaling peaks and obstacles to acquire the skills to satisfy their lofty ambitions. This path can prematurely accelerate development, flinging back with as ferocious a velocity as what moved them forward. However, they recognize the gain, even amid failure, which will prepare them for their next pursuit.

Throughout my career I have witnessed individuals who chose an extremely specific path to professional success, whether the line was curved, straight or both.

For example, I once worked with an interesting site director who hosted me throughout a complicated site evaluation visit. His knowledge of the financial and operational elements required to support the protocol at the institution exceeded the requisite. His passion and care for the investigational site personnel under his management surpassed expectation. This led me to believe that he was the site owner, and I asked him to share his journey to site ownership.

"Michael" started as a study coordinator at a neurology research practice. After three years in that position, he wanted more of a challenge and decided to become a CRA, the presumed natural progression. He flourished in that role and became a senior CRA in less than five years. After several more years in that position, it became clear that he was not designed to work for an organization; he was fiercely independent and desired a more substantial role in study development in which he could foster positive change for study participants. He had considered opening a research site, as he had a business degree to complement his diverse research background. Partnering with an investigator, he opened his first site less than two years later. They specialized in neurology trials and in five years their research organization had grown to operate several successful sites within the region. His innovative nature steered him off the linear path that had once served him, and though the course was challenging, the outcome was beyond his wildest dreams.

"Suzy" was a colleague I had met through attending an international conference sponsored by a prominent CRO to which we both belonged. We served together on several committees and developed a strong friendship. She attributed her success as an independent clinical research consultant to her pursuit of a non-traditional path. Though she started her CRA career with a large CRO, after several years she felt organizational constraint and longed for the independence of contracting. She decided to start her own CRA consulting business and described the first few years as the "frightening unknown." She was forced to learn the tax elements and implications of a small business and the importance of marketing to draw clients for sustainability. However, she stuck with it and developed a network of clients that brough consistent project work for a number of years. After a decade of success as a contract CRA, she decided to move into a quality role and soon established herself as a successful independent quality auditor. She conducted numerous GCP audits for clients and developed a solid reputation in that challenging space. She has described herself as not suited for traditional organization progress and attributes her success to her willingness to take risks.

I once worked with an ambitious CRA who plotted her linear career course with extreme finesse, with the goal of becoming an executive director or vice president of a prominent research organization. She started her career as a research nurse and progressed to the CRA role after several years of institutional experience. Within a period of 10 years, she moved from a senior CRA role to a senior manager role. Within a period of 20 years, she had been promoted to executive director of clinical operations

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Data-Sharing, Collaboration Key to Successful Implementation of AI in Clinical Research

*In this second installment of a two-part series, **Dan Ayala**, chief security and trust officer for R&D software developer Dotmatics, addresses the critical need for sponsors to ramp up their AI readiness and collaborative capabilities in the face of a rapidly changing clinical research landscape.*

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In today's environment, collaborative mindsets and practices are critical, but they can be a tall order to fill, especially for those research units that aren't used to or prepared for working so closely together, he says.

"Whether it's chemists and biologists collaborating on chemically modified biologics, or internal and external partners working on projects across modalities and diseases, teamwork is more important than ever. Unfortunately, it's not always easy," Ayala says. "Many R&D groups, who have long worked in relative isolation, are now required to collaborate and share data, which requires shifts in mindset and culture. It also requires a governance and execution shift."

"Bespoke and insulated research teams don't have the systems and processes in place to share and hand off well-annotated data while at the same time controlling access, tracking changes, and ensuring good data practices are followed by all participants and collaborators," he continues.

For many organizations, efficiently and safely sharing data between research teams while safeguarding data integrity is a challenge as well, with the varying ways collaborators handle instruments, software, workflows and data types complicating an already complex task. Structured and unstructured data, for instance, wind up scattered across multiple repositories and mediums rather than being stored in a secure, central and standardized data repository that affords appropriate access and uses a well-defined data governance framework.

Hurdles surrounding data-sharing have grown so frequent that industry efforts have emerged aimed at standardizing the critical process of data management. The Findable, Accessible, Interoperable and Reusable (FAIR) guiding principle is one high-profile example in the realm of scientific data management. Becoming compliant with these principles requires organizations to change the format, model and storage of their data and the way they integrate their systems.

"This can seem overwhelming, but the change can be done incrementally. It's not an all-or-nothing proposition," Ayala explains. "Whether a company is building a comprehensive FAIR-compliant informatics ecosystem or adopting a data analysis and graphing solution that embraces FAIR data principles, moves toward implementing FAIR-aligned methods can pay dividends in time savings, reproducibility of research, improved knowledge sharing and AI-readiness."

AI has become a globally recognized tool, not just across many aspects of daily life but in clinical research as well. As AI finds its way into R&D, organizations will require data infrastructures to properly capture and manage proprietary data that will differentiate their research, Ayala says. For many, this involves taking the first step of adopting technology and processes that support massive growth in data volumes, dismantle data silos, integrate custom software and systems and normalize data.

The end goal, he says, is to make all data trustworthy, well-structured, correlated, shareable and ready for use in AI models. The complex workflows, data types and systems of the life sciences industry make this a uniquely challenging endeavor, but it is a critical goal nevertheless.

Regulators are currently working to incorporate AI and machine learning considerations into global compliance regulations. In March, for example, the EU passed the Artificial Intelligence Act, a landmark piece of legislation that addresses the protection of human health, safety and fundamental rights in the context of AI and its use by a broad array of industries, academia, government and civil organizations. According to Ayala, now is a pivotal moment for companies to appraise their existing processes and systems with an eye for supporting regulatory and ethnical challenges surrounding AI, including the assurance of data integrity, security, traceability and bias limitation.

"The alignment of data management and integrity are vital to long-term research success and preparation for the automated, connected and collaborative future of research," Ayala says. "Fortunately, today's scientists have a wide range of tools to easily manage, search and visualize their R&D data, with the future being led by solutions that can unite all those applications that produce and analyze data within one secure data management platform."

Team Building

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cessfully assembling, managing and supporting a multigenerational team in clinical research requires a focus on inclusive hiring practices that draw from a diverse pool of ages, backgrounds and skills.

Tailored training programs are essential to meet the learning preferences of each generation. Implementing flexible working policies can accommodate the varied life stages and commitments of team members, particularly in a remote work setting in which flexibility is paramount.

Establishing mentorship programs (traditional and reverse mentorship) allows employees to share insight and expertise, fostering mutual growth and learning. Recognizing and rewarding contributions in ways that resonate with different generations, from formal acknowledgments to digital badges, is also crucial in maintaining a motivated and cohesive team, especially when team members are dispersed across different locations.

CWM: What is essential to communication within these teams? For example, how do generational differences impact communication between team members and how can this be addressed?

CG: Effective communication within multigenerational teams relies on driving awareness of when and how to leverage various channels, encouraging feedback across all levels what and strengthening listening skills across the team. Utilizing diverse communication platforms, such as email, instant messaging and video calls, caters to the varying preferences of team members when used properly.

With so many options, knowing which channels to leverage can be overwhelming. You can help your teams by setting clear expectations regarding communication practices and response times to prevent misunderstandings. Providing training on effective communication and the use of various tools ensures that everyone can engage comfortably.

The shift to remote work has amplified the need for robust digital communication tools and clear virtual communication strategies to bridge generational gaps and maintain team cohesion. Promoting cultural sensitivity is also particularly important in a diverse team and fosters mutual respect and understanding.

CWM: What conflicts can arise due to generational differences and how can these conflicts be mitigated and resolved? Where are conflicts seen most frequently in the workplace?

CG: Conflicts arising from generational differences often stem from varying work styles, with some team members preferring independent work and others leaning towards collaboration. Communication preferences can also differ, with some favoring face-to-face interactions and others preferring digital communication.

Disparities in comfort levels with new technology can also lead to friction. In a remote work environment, these conflicts can be exacerbated by a lack of in-person interactions and reliance on digital tools.

To mitigate and resolve these conflicts, it is beneficial to provide awareness training on generational differences and the value each generation brings. Conflict resolution training equips managers to mediate effectively, and fostering collaboration through cross-generational projects can build understanding and respect. Regular check-ins, both virtual and in person when possible, help address and resolve issues early, maintaining a harmonious work environment.

CWM: What considerations should be made for selecting/using communication channels within these teams and their organizations? What role does technology play in this area?

CG: It's important to choose those that best suit the message and audience and understand how to optimize each channel. Detailed reports might be best shared via email with a follow-up meeting to answer questions or facilitate dialogue, while quick updates could be handled through instant messaging. Meanwhile, difficult or complex messages should be addressed in a face-to-face meeting, in-person or online to enable questions and help team members gain clarity and understanding. Keep in mind that, in the context of remote work, technology plays a critical role in facilitating communication, collaboration and maintaining a sense of connectedness among team members who are physically apart.

Ensuring that the chosen technology integrates seamlessly with existing systems and is user-friendly for all team members is crucial. Accessibility is another key consideration; communication tools should be easy to use for team members with varying levels of tech proficiency.

Security is paramount to protect sensitive information, and continuous evaluation and updating of communication tools helps keep pace with technological advancements and evolving team needs.

CWM: How can teams best navigate, adapt to and communicate organizational changes? Are organizational changes in our industry impacting clinical research teams?

CG: Navigating organizational change as a team involves clear communication to ensure understanding of the reasons for change, its expected impact and the role of the team in supporting the change. Identifying strong change agents and involving team members in the change process increases buy-in and reduces resistance. Providing resources and support, such as training and counseling, helps teams adapt to changes more smoothly. Establishing feedback loops allows for monitoring progress and addressing concerns. And don't forget to celebrate accomplishments and key milestones along the way.

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Team Building

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The clinical research industry is currently experiencing frequent organizational changes due to regulatory updates, technological advancements and market demands. These changes can cause uncertainty and stress, making it crucial to manage transitions smoothly to maintain team morale, engagement and productivity.

Tailoring communication and support to meet the varied needs of different generations ensures that everyone feels informed and valued, helping teams collectively adapt to change more effectively. For remote work, it is particularly important to use digital platforms to communicate changes clearly and ensure that all team members, regardless of their generational background, are on the same page and feel supported throughout the transition.

Warning Letter

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ing reports lacked reviewed documents and communications with site staff, including whether monitoring efforts included checking source documents with CRFs.

It's essential to have a detailed study monitoring plan in place and follow it to a T, advises Trevor Cole, associate director for Avoca, a WCG company, to show clearly that the sponsor is diligent in maintaining trial quality, compliance and confidence.

"Reports should document the monitoring activities detailed in alignment with the monitoring plan that illustrate what was monitored, when it was monitored, by whom, and observations or action items from the monitoring activities," he tells *The CenterWatch Monthly*. "Sponsors should also have procedures describing monitoring, handling of protocol deviations and investigator noncompliance. In addition, sign off on CRFs should be completed in timelines documented in study plans and contemporaneous to results, when possible."

The second issue, failure to select qualified investigators and monitors by training and experience, resulted from Nobles' lack of documentation that showed investigators fit the bill. In addition, the sponsor could not produce documentation showing it was qualified to monitor the trial. In any monitoring plan, it's important to cover the task of qualifying and logging the qualification of investigators.

Individuals conducting monitoring should be qualified by education and experience, and that qualification needs to be documented in the trial master file (TMF), Cole says.

The third and fourth violations are tied to failures to obtain signed agreements from each investigator. Here, while all investigators provided these, they did not include statements committing to supervising all testing of the investigational device that involved participants.

Additionally, they didn't include sufficient financial disclosure information, with the sponsor unable to provide financial disclosure records for any site during the agency's inspection.

To avoid these problems, systematic verification of financial disclosure/conflict of interest forms and investigator agreements should be built into a sponsor's site activation process, and trial tasks should not begin at a site until this verification occurs, Cole recommends.

"When checks are in place to activate a site, these key steps are assured in advance of a site having the notification of activation and thus activities should not occur at the site in advance of those key requirements being met," he says.

Overall, it is essential that monitoring delivers assurance of investigator oversight and involvement to validate that participant safety and protocol compliance are prioritized. With this in mind, investigators need to be well-versed in trial expectations for oversight and involvement and how these are documented, and they need to carry out these duties in as close to real time as possible.

Multisite trials in particular require special care and consideration when it comes to coordination, especially when it's an organization serving as the sponsor, Cole says.

"Closely ensuring all site activation and site maintenance steps are accounted for and documented in the TMF is essential. Site activation should include the documentation of investigator and site qualifications to deliver on study expectations as well as the documented training of the study protocol or unique assessments prior to engaging on delegated study duties," he says.

Ultimately, the sponsor failed to take the key step of submitting a written response to the Form 483. Presenting a convincing correction/prevention plan to the FDA can head off the threat of a Warning Letter.

Read the full Warning Letter here.

Viewpoint

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for a prominent research organization. Coincidentally, during that period she served as my line manager at one organization, and most recently the regional head of another organization where I was employed. She stayed true to her career master plan and reaped incredible professional rewards for her dedication.

At the end of the day, professional development is a highly personal choice that requires strength and insight to reach ambitious goals. The chosen path does not matter as long as the journey provides the knowledge to treat and protect the patients we serve as our collective outcome.

Study Lead Opportunities

CenterWatch analyzes data in its drug intelligence database to provide advance notice of clinical trials expected to enter the next phase of clinical development soon. Contact information is provided for follow-up. **Sponsors/CROs:** to list an upcoming trial here, contact Leslie Ramsey, 703.538.7661, lramsey@wcgclinical.com.

Company name	Drug name	Indication
phase 1		
Biond Biologics	BND-35	Advanced cancer
BridGene Biosciences	BGC515	Advanced solid tumors
Eirion Therapeutics	ET-02	Androgenic alopecia
Quanta Therapeutics	QTX3046	KRASG12D-mutated advanced solid tumors
phase 1/1b		
GenVivo	GEN2	Advanced solid tumors
phase 1b		
HOOKIPA Pharma	HB-500	HIV
Neumora Therapeutics	NMRA-511	Alzheimer's disease agitation
phase 1/2		
Dynavax	Z-1018 shingles vaccine	Active immunization against shingles
Tubulis	TUB-040	Platinum-resistant high-grade ovarian cancer or relapsed/ refractory adenocarcinoma non-small cell lung cancer
phase 2		
Allogene Therapeutics	Cemacabtagene ansegedleucel	First-line treatment for large B-cell lymphoma patients likely to relapse
Alto Neuroscience	ALTO-101	Cognitive impairment associated with schizophrenia
Cartesian Therapeutics	Descartes-08	Systematic lupus erythematosus
Merus	Petosemtamab	Second-line metastatic colorectal cancer
Palatin Technologies	Bremelanotide	Erectile dysfunction
phase 2b		
Kiniksa Pharmaceuticals	Abiprubart	Sjögren's disease
phase 2/3		
Sustained Therapeutics	ST-02	Upper tract urethral carcinoma
phase 3		
Arthrosi Therapeutics	AR882	Gout
Intensity Therapeutics	INT230-6	Advanced soft tissue sarcomas
iTeos Therapeutics	Belrestotug plus dostarlimab	First-line advanced unresectable or metastatic PD-L1 high non-small cell lung cancer
Ocugen	OCU400	Retinitis pigmentosa
Quince Therapeutics	EryDex	Ataxia-telangiectasia

FDA Actions

The following is a sampling of FDA regulatory actions taken during the previous month, compiled from CenterWatch and third-party sources, including the FDA and company press releases. For more information on FDA approvals, visit centerwatch.com/fda-approved-drugs.

Company name	Drug name	Indication	FDA action
Abata Therapeutics	ABA-101	Progressive multiple sclerosis	IND approved
Avalo Therapeutics	AVTX-009	Hidradenitis suppurativa	IND approved
Biostar Pharma	Utidelone injection	HER2- breast cancer brain metastasis	IND approved
EG 427	EG110A	Neurogenic detrusor overactivity in spinal cord injury patients	IND approved
GT Biopharma	GTB-3650	Relapsed/refractory CD33+ hematologic malignancies	IND approved
Immorna Biotherapeutics	JCXH-211	Malignant solid tumors	IND approved
iRegene Therapeutics	NouvNeu001	Parkinson's disease	IND approved
KaliVir Immunotherapeutics	VET3-TGI	Advanced solid tumors	IND approved
KBio	EV68-228-N	Acute flaccid myelitis	IND approved
Rgenta Therapeutics	RGT-61159	Adenoid cystic carcinoma and colorectal cancer	IND approved
SCG Cell Therapy	SCG142	HPV-associated solid tumors	IND approved
Vir Biotechnology	Tobevibart and elebsiran	Chronic hepatitis delta infection	IND approved
Eli Lilly	Kisunla (donanemab-azbt)	Early symptomatic Alzheimer's disease	Approved
Verona Pharma	Ohtuvayre (ensifentrine)	Chronic obstructive pulmonary disease	Approved
argenx	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)	Adult patients with chronic inflammatory demyelinating polyneuropathy	Approved for new indication
Arcutis Biotherapeutics	Zoryve (roflumilast) cream 0.15%	Mild-to-moderate atopic dermatitis in patients 6 and older	Approved for new formulation
Endotronix	Cordella Pulmonary Artery Sensor System	Class III heart failure	Approved

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