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January 13, 2020

Static Salaries, Lack of Opportunity Blamed for Five-Year High in U.S. CRO Trial Monitor Turnover

By Leslie Ramsey

Nearly 30 percent of CROs' clinical research monitors in the U.S. left their jobs in 2018, a 4 percentage point jump over previous years, according to a new global workforce survey.

CRA turnover had hovered around 25 percent from 2014 to 2017 but shot up to 29.4 percent in 2018, says a report from consulting firm BDO USA. By comparison, the general industry turnover rate in the U.S. is approximately 19 percent per year.

BDO's CRO Industry Global Compensation and Turnover Survey collected workforce data, including hiring, salary structure, benefits and incentive programs, from 26 CROs in the U.S. and other countries.

Foreign CROs fared better than their U.S. counterparts, the survey found, with only 16.3 percent turnover in 2018, possibly due to smaller countries' less intense travel requirements. Countries matching the U.S. in turnover rates in 2018 were Ireland at 33 percent, China at 32 percent and Sweden at 30 percent.

A major factor in the overall high rate of turnover is lack of salary growth. CROs' compensation increases have mostly held steady at about 3 percent annually and generally have not matched growth in employee experience. Salary increases on average actually declined to 2.9% in 2018 and 2019 after rising 3% in 2016 and 2017 while general industry increases rose to 3.2% in 2019 and 3.1% in 2018.

see **Static Salaries, Lack of Opportunity** on page 7 »

Highlights from WCG Clinical Research Trends & Insights Report

Every year, WCG Clinical asks a number of thought leaders about what they think is coming in their areas of expertise for the coming year. In a two-part piece featured last week (*CenterWatch Weekly*, Jan. 6, 2020) and this week, 10 subject matter experts from WCG and our partners share the important shifts, trends, regulations and priorities that will inform clinical trial development in 2020 and beyond.

The insights and predictions are grouped into six topics. They are: Scientific Advancements, Study Design and Study Conduct, Technology & Data, Public Policy & Regulatory Oversight, and Patient Advocacy. To read the full report, click here: https://bit.ly/2FIUnRX. Below are five experts:

- **MARK SUMMERS**
  President, Patient Engagement Division, WCG

Placebo response reduction represents a tremendous opportunity in studies with subjective outcomes measures, such as those within the CNS specialties. Placebo response continues to cloud accurate signal detection and clinical endpoint measurements with huge costs in terms of inaccurate outcomes tracking and even failed trials.

New analytical tools have been introduced that allow clinical and data scientists to employ an automated rules engine, customized for the specific study design and patient population, to perform ongoing analyses of data in near real-time to spot outliers while data is being captured during a study — rather than having to wait for an interim analysis or study completion — in much the same way an onboard computer monitors automotive

see **Highlights from WCG** on page 6 »

Industry Briefs

Funding for AI in Clinical Trials Decreasing, New Report Says

Reversing a two-year trend, total investment for using artificial intelligence (AI) in clinical research and drug development dropped 23 percent in 2019, according to a new research report.

Signify Research, a healthcare technology analysis firm, looked at funding of start-ups focused on creating AI tools for drug development and clinical trials. After a high of $1.7 million in 2018, investments dropped to $1.3 million in 2019. The report says 54 percent of funding went to information synthesis efforts, 32 percent went to drug design activities and 14 percent to clinical trial applications.

The decline in funding new AI solutions for clinical trials reflects investors' and sponsors' desire to see more evidence and proof-of-concept of the technology's value in clinical trials, says the report.

To read the report, click here: https://bit.ly/2T9ebWA.

China Updates Requirements for Medical Device Clinical Trials

China's National Medical Products Administration (NMPA) updated its clinical trial regulations for medical devices last month, designating eight device categories that require clinical trials. It also added new exemptions from clinical trial requirements, allowed conditional approval with limited clinical data and published guidelines on the use of real-world data (RWD).

The eight Class III device types include a variety of implantables, such as cardiac pacemakers, blood pumps and orthopedic implants. NMPA says it will accept data from trials outside China for these devices.

Exemptions for 40 class III devices, 108 class II devices, and 23 class III IVDs were added to the new clinical trial rules. There are now 1,002 medical devices and 401 IVDs that are exempted from trials in China. The new exemptions were included in the NMPA update to make clinical exemptions of devices more consistent with internationally accepted standards, says Leon Lei of consulting firm ChinaMed Device.

Additionally, the new changes from the NMPA state that conditional approval can be granted to devices indicated for life-threatening diseases, particularly if the benefits of the device outweigh potential or known risks. For conditional approval to be granted, the manufacturer of the device must commit to performing additional clinical trials on their product(s).

NMPA also described 11 situations in which RWD can be used to support clinical trials. They include the use of RWD as an external control for single-group experiments, to evaluate treatments of rare diseases and for postmarket surveillance.

For more information on these developments, register for the FDAnews webinar on the topic on Jan. 21: https://www.fdanews.com/chinanmpa.

UK Calls for Complex Innovative Design Trials to Study Cancer Therapies

Despite the potential of complex innovative design (CID) trials, there are no practical guidelines in Europe that focus on how to perform these trials, according to a UK cancer research organization.

The Experimental Cancer Medicine Centres (ECMC) working group lists 10 recommendations for creating innovative trials, including early regulator involvement in design, training and support for participants, anticipating future protocol modifications, flexible statistical methods and a trial management group to oversee the studies. The consensus statement also recommends timely dissemination of trial results, pathways for accelerated approval, analysis of trials' impact on public health, staff training in complicated methodologies and using practical patient materials, such as a trial handbook.

The CID model the ECMC is pushing for mirrors that of the adaptive clinical trial design in the U.S., which the FDA recently issued guidance on (*CenterWatch Weekly*, Dec. 9, 2019).

To read the ECMC statement, click here: https://go.nature.com/2FxhPSg.

Finland Modernizes Clinical Trial Regulations

Clinical trials in Finland must report adverse events right away rather than in a quarterly report, according to revised regulations from the Finnish Medicines Agency — Fimea.

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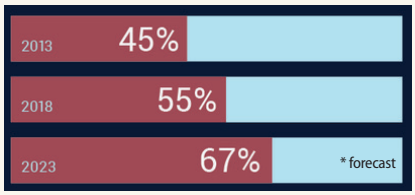
Data Point

Percent of Trials with Outsourced Data Monitoring Committees (DMCs) and Endpoint Adjudication Committees (EACs)



Source: L.E.K. survey, interviews and analysis

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Beth Belton Editorial Director
Stephanie Akers Production
Russell Titsch Business Development Director

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CenterWatch Main and Editorial Offices
300 N. Washington St., Suite 200, Falls Church, VA 22046
editorial@centerwatch.com / sales@centerwatch.com

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Industry Briefs

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Prior regulations required a quarterly or semiannual report of adverse events. Under the revision, sponsors must report adverse events to Fimea no later than seven days of becoming aware of the events. Serious unexpected adverse reactions that are not life-threatening or fatal must be reported within 15 days.

The regulations, which took effect Jan. 1 now mirror what is required in the U.S.

Another change in the regulations is that trial materials now must be submitted electronically via the Common European Submission Portal and its associated secure mail service. In the past, they were submitted as signed hardcopy documents.

In addition, all trial results must be submitted to the EU register of clinical trials, EudraCT. Other changes to Fimea's clinical trial regulations include an update on the definition of an interventional clinical trial and requirements concerning the labeling of investigational medicinal products.

To read the regulations, click here: https://bit.ly/2T8sF9q.

Amylgen and Neuron-Experts Partner to Evaluate Potential Alzheimer's Drugs

Two CROs in France are joining forces to create a comprehensive offering of in-vivo and in-vitro efficacy evaluation for neurodegenerative disease compounds.

Amylgen will combine its portfolio of in vivo tests with Neuron-Experts' in vitro assessments to give investigators a single source of tools to identify the most promising drug candidates.

The partnership initially will focus on treatments for Alzheimer's disease but plans to expand its assessments to other neurodegenerative diseases.

Veristat Expands Reach in Europe by Acquiring The Clinical Trial Company

To improve its presence in the European market, Veristat has acquired The Clinical Trial Company (TCTC Group), a CRO headquartered in Knutsford, UK.

TCTC Group focuses on gene and cell therapy, orphan disease and central nervous system trials. This buy follows another European acquisition by Veristat made just four years ago, when it bought out UK-based Spero Oncology.

Up and Coming

This feature highlights changes in clinical trial organizations' personnel.

Antengene Corporation

John Chin is now the chief business officer of Antengene, joining the company after serving as the country general manager at Celgene China.

Aridis Pharmaceuticals

Aridis has named **Michael A. Nazak** its new chief financial officer. Prior to this appointment, Nazak served as the company's vice president of finance. Before joining Aridis, Nazak was the senior vice president of finance at Coherus Biosciences. Nazak will be replacing Fred Kurland, who has recently retired from the company.

Arrowhead Pharmaceuticals

James Hassard has been appointed to the newly created position of chief commercial officer at Arrowhead Pharmaceuticals. Since 2016 and prior to joining Arrowhead, Hassard served as senior vice president of marketing and market access at Coherus BioSciences.

AsclepiX Therapeutics

Theresa G. H. Heah has been appointed the position of chief medical officer at AsclepiX Therapeutics. Prior to this role, Heah served as the chief medical officer at Applied Genetic Technologies.

AVEO Oncology

AVEO Oncology has appointed **Erick Lucera** as chief financial officer after recently serving as chief financial officer of Valeritas.

AzurRx BioPharma

Daniel Schneiderman has been appointed chief financial officer of AzurRx BioPharma. Schneiderman's most recent position was chief financial officer for Biophytis, a role he held from November 2018 to December 2019.

BeyondSpring

BeyondSpring has appointed **James Tonra** as the firm's new chief science officer. Tonra previously served as BeyondSpring's senior vice president of preclinical development.

Biocon Biologics

Biocon Biologics has appointed **M.B. Chinappa** to the position of chief financial officer of its subsidiary Biocon Biologics India. Before this appointment, Chinappa was the president of finance and chief financial officer of Biocon's subsidiary company Syngene International.

BioDelivery Sciences

Kevin Ostrander has been named senior vice president of business development and member of the company executive leadership team of BioDelivery Sciences. Ostrander joins the company after previously serving as the head of North America business development at Glenmark Pharmaceuticals.

Biofrontera

Business operations of the American Biofrontera subsidiary will now be managed by **Christopher Pearson**, chief commercial officer USA, and **Erica Monaco**, chief financial officer USA. Sales, marketing and market access will be managed by Pearson, whereas finance and operations, human resources, and legal and compliance will be managed by Monaco.

Cambrex

Cambrex has named **Robert Green** as the firm's new executive vice president and chief financial officer. Prior to this appointment, Green was the chief financial officer of General Electric Power. **Shawn Cavanagh** has been promoted to president and chief operating officer at Cambrex, after serving as the company's executive vice president and chief operating officer since 2011. Additionally, Cambrex has promoted **Stephan Haitz** as Cambrex's president of CDMO sales and marketing, after serving as the firm's vice president of sales and business development.

Carisma Therapeutics

Carisma Therapeutics has named **Debora Barton** as the company's new chief medical officer. Prior to this appointment, Barton was senior vice president of clinical and safety at Iovance Biotherapeutics. Carisma Therapeutics has also appointed **Tom Wilton** to the role of chief business officer. Previously, Wilton was the chief business officer of LogicBio Therapeutics, Inc.

CARsgen Therapeutics

Yong Fan has been named the senior vice president of global regulatory affairs of CARsgen Therapeutics. Before accepting this appointment, Fan was A2Z Reg Solutions' senior consultant and owner and a member of ISCT Legal and Regulatory Affairs North America Committee.

Columbus Organization

Columbus Organization has promoted **Jeff Klimaski** to the role of CEO and president. Prior to this promotion, Klimaski served as the company's president and chief operating officer.

ControlRad

ControlRad, a medical technology company based in Atlanta, has named **Peter Pizzo** as the firm's chief financial officer. Recently, Pizzo was the chief financial officer of Cartiva. ControlRad has also named Joe Ross as vice president of marketing. Ross most recently served as Zimmer Biomet's general manager of the company's spine division. Additionally, **Amy Lazarus** was named the company's new vice president of USA operations. Lazarus' prior appointment was managing director at ArchPoint Consulting.

Cyclica

Melissa Landon has joined Cyclica as the company's new vice president, chief

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Up and Coming (continued from page 4)

strategist. Before taking this appointment, Landon was the director of applications science at Schrödinger.

Enzo Biochem

Enzo Biochem has named **Rebecca J. Fisher** to the company's board of directors, replacing newly retired board member Gregory M. Bortz. Fisher is the chief financial officer of Bellevue Hospital in New York. Enzo has appointed Fisher to the audit, compensation and nominating/governance committees, and she also now serves as the chair of the audit committee.

Fountain Medical

Ling Zhen has joined Fountain Medical, a China-based CO, as the company's new co-chairman of its board of directors as well as the company's new CEO. Prior to joining Fountain, Zhen served as a partner at Draper Dragon Venture Group and also spent more than 12 years at IQVIA in the role of global senior vice president and the general manager of Greater China.

Intrexon

Helen Sabzevari has been named the CEO of Intrexon, now known as Percigen. Sabzevari was previously the president of the company's subsidiary.

Invicro/Konica Minolta Precision Medicine

Matthew Silva has been appointed CEO of Invicro, a Konica Minolta company. Silva, who has also recently joined the company's board, was previously the executive vice president of scientific applications at Invicro. Jack Hoppin, Invicro's cofounder and most recent CEO, will be replaced by Silva. Hoppin will now serve as the president of Konica Minolta Precision Medicine.

Ironshore Pharmaceuticals

Dave Lemus has been named Ironshore Pharmaceuticals' new chief financial officer. In the past 20 years, Lemus held several executive management roles at various pharmaceutical and biotechnology firms. Ironshore has also promoted **Peter Lammers** to the position of chief commercial officer. After joining Ironshore from IQVIA, Lammers was the company's senior vice president of commercial operations.

Kura Oncology

Kirsten Flowers has been named chief commercial officer at Kura Oncology, joining the company after serving as head of commercial operations at Array Biopharma.

MBX Biosciences

Kent Hawryluk has been appointed to the position of president and chief executive officer of MBX Biosciences. Hawryluk, a co-founder and member of MBX's board of directors, was also a co-founder and most recently chief business officer of Avidity Biosciences. MBX has also named **Greg Davis**, to the position of vice president of product development. Davis previously served as vice president of CMC, regulatory and quality at Calibrium.

Mirati Therapeutics

Mirati Therapeutics has announced the appointment of **Daniel R. Faga** to the position of executive vice president and chief operating officer. Most recently, Faga was the chief business officer at Spark Therapeutics. **Benjamin J. Hickey** was appointed as Mirati's executive vice president and chief commercial officer. Previously, Hickey was the senior vice president and chief commercial officer at Halozyme Therapeutics. Additionally, Mirati has promoted **Vickie S. Reed** to the position of senior vice president of finance and chief accounting officer. Mirati has also promoted **Jessica M. Corson** to the role of vice president of business development.

Momenta Pharmaceuticals

Momenta Pharmaceuticals has appointed **Young Kwon**, the company's chief business officer, to the new position of chief financial and business officer. This change comes after Momenta's consolidation of key financial and business functions under Kwon.

Phathom Pharmaceuticals

Phathom Pharmaceuticals has appointed **Martin J. Gilligan** as the firm's chief commercial officer. Most recently, Gilligan was the corporate vice president at Celgene.

Rhythm Pharmaceuticals

Keith Gottesdiener, CEO of Rhythm Pharmaceuticals, has announced his departure from the company following completion of Rhythm's new drug application. Gottesdiener's move will likely come at the end of the first quarter.

SGI-DNA

SGI-DNA has appointed **Brian Donnelly** to the position of chief commercial officer. Previously, Donnelly was the global head of customer solutions and head of global commercial strategy at Illumina.

Silicon Therapeutics

Humphrey Gardner has been named Silicon Therapeutics' new chief medical officer. Prior to this appointment, Gardner was the chief of medical oncology at Evelo Biosciences. In addition, Silicon has named **Christopher Borella** as the company's new vice president and head of operations. Borella recently spent over eight years at Agios Pharmaceuticals, where he served as the company's head of early-stage program management. **Huafeng Xu** has been appointed to the position of Silicon's chief technology officer. Before joining Silicon, Xu sent 12 years at D. E. Shaw Research.

Turning Point Therapeutics

Homa Yeganegi has been appointed to the roles of senior vice president, project team leader and head of medical affairs at Turning Point Therapeutics. Previously, Yeganegi was senior vice president and global program leader at Halozyme.

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engine performance while driving. A clinician can then perform root-cause analysis to determine the reason for the anomaly and follow up with immediate implementation of corrective procedures, such as retraining the site or patient in specific areas, including process control or symptom capture and reporting.

These new early warning tools are equipping scientists with the ability to significantly decrease placebo response along with corresponding risk and cost in studies with subjective outcomes.

- **KARMEN TRZUPEK, MS**
  Director, Clinical Trial Services, InformedDNA

Until recently, genetic testing in clinical trials has been performed primarily to screen patients with rare genetic diseases, such as cystic fibrosis. Increasingly, genetic testing is being used in more common multifactorial diseases, such as Alzheimer's disease and age-related macular degeneration, in which multiple genetic risk factors, in combination with environmental and lifestyle factors, can ultimately lead to disease.

In the past 15 years, more than 500 clinical trials have been conducted in Alzheimer's disease, to nearly universally disappointing results. Trial sponsors are now being urged to test patients for different genetic risk variants in APOe to balance the treatment and placebo arms of their studies. APOe4 is a genetic-risk variant that can increase an individual's risk of developing Alzheimer's disease by up to 11-fold. Very recent data, published in November 2019, suggests that the APOe2 variant carries even more significant weight regarding disease risk -- but this particular variant is protective. (Individuals who have 2 APOe2 variants have up to a 99.6% lower risk of developing Alzheimer's disease compared to someone with 2 APOe4 variants.)

Clinical trial participants in future studies will likely be tested for these genetic variants prior to assignment to a study arm to ensure that observed disease-progression differences can be attributed to the experimental therapy, and not underlying genetic risk.

It's clear that in the near future genetic testing will be increasingly used to evaluate and stratify study populations even when the therapeutic isn't a gene therapy.

- **DANIEL KAVANAGH, PhD, RAC**
  Senior Scientific Advisor, Gene Therapy, WCG

With regard to clinical product development in the coming year, I am looking forward to seeing new proof-of-concept approaches to cancer treatments that make use of advanced synthetic biology. Synthetic biology is the application of engineering principles to molecular biology, especially through the combination of validated, modular synthetic DNA and RNA components. These approaches will make future human gene transfer products more effective and responsive to clinical needs.

Currently the FDA has approved two chimeric antigen receptor T-cell (CAR-T cell) products, both for the treatment of B cell malignancies. Both products are based on genetic modification of the patient's lymphocytes to recognize a single tumor antigen (CD19). Both products are always "on"— in attack mode, seeking to destroy CD19 targets. These products, the result of heroic development efforts, represent the first generation of gene-modified immune therapies.

Ideally, future CAR-T therapies will not be restricted to a single tumor antigen target; they will be "tunable," with response intensity under the control of the treating physician; they will be versatile in terms of the selection of cell contact-dependent and -independent immune effector mechanisms they deploy; and they will incorporate genetic logic circuits —molecular computers — to execute programmable responses to changing clinical needs at the cellular level. In principle, the necessary design elements exist today, but practical deployment of these ideas will require careful planning and intense efforts to address clinical, commercial, regulatory and long-term safety needs.

- **MARK OPLER, PhD, MPH**
  Chief Research Officer, WCG MedAvante-ProPhase

2020 will be another exciting year for psychiatry and neuroscience clinical trials. The overarching story for 2020 will be one of "building momentum" — taking the achievements and gains of the past decade to the next level.

FDA approvals of new rapid-acting agents for mood disorders, such as esketamine and brexanolone, signal that the new era of CNS research is firmly rooted and poised to continue. Ongoing trials of PTSD, non-dopaminergic mechanisms for treatment of schizophrenia and continued progress in rare neurodevelopmental disorders all show that the industry continues to blaze new trails. This exciting flurry of activity in drug development comes at a time when entirely new paradigms are being constructed in digital therapeutics, i.e., "Digital Medicine (DiMe)," and novel applications of devices. We need to remember, however, that these advances have coincided with some notable stumbles in the face of high placebo response, causing massive late-stage failures and killing off promising avenues of investigation.

The extent of the progress we make in the next decade depends on the degree to which we address the rising cost and complexity of research, refine the role of technology to enable progress, and confront the ever-present issue of placebo response in neuroscience and beyond. The challenges and the opportunities of 2020 and the years to follow are considerable, requiring all stakeholders to find common ground and work together to achieve success.

- **STEVE SMITH**
  President, Patient Advocacy, WCG

In 2020, patient advocacy will continue to transform drug development, although positive results can be hard to see

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unless one takes a long-term look at the past for context. We see healthy skepticism that drug developers' patient-centric efforts create real change. Protocols are still overloaded with burdensome procedures, endpoints don't reflect what matters most to patients and dialogue with patient communities seems symbolic, even off-putting when informed consents and trial descriptions remain in complex language many patients don't understand. Patients note how warmly trial sponsors reach out to them at first, then disappear, sharing neither trial outcomes nor the patient's own data.

As discouraging as this sounds, patient/researcher collaboration continues the detailed work to transform this atmosphere. Today's hard work stems from profound legislative changes to regulatory processes that collaborating patient advocates brought about in the past. It takes years to realize the benefits of such change, e.g., The Orphan Drug Act (1983), PDUFA V (2012) and 21st Century Cures Act (2016).

Five years from now, looking back at 2020, we will confirm improvements in the use of patient-friendly lay language, patient cohorts providing advice at trial design time, researchers sharing patient data with any legitimate researcher when collected in a federally funded trial, patient-friendly, online ways to search for trials and increasingly better-informed patients who have something positive to say about participation in clinical research.

Static Salaries, Lack of Opportunity

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"CRAs typically have a steep learning trajectory early in their career, which makes them very valuable after a few years of hands-on experience," the report says.

CRAs with three to five years under their belts are likely to have reached a skill level that outpaces their paychecks. "Unsurprisingly, many of these employees view switching companies as their best career choice."

The report also cites CRA burnout from long hours and extensive travel, as well as an increase in merger and acquisition activity, which "disrupts relationships and creates uneasiness among employees."

The cost of CRA turnover can be difficult to estimate but sourcing, recruiting and onboarding expenses make up about 33 percent of annual employee earnings. "Harder-to-measure costs include productivity interruptions and loss in knowledge/intellectual capital," the report says.

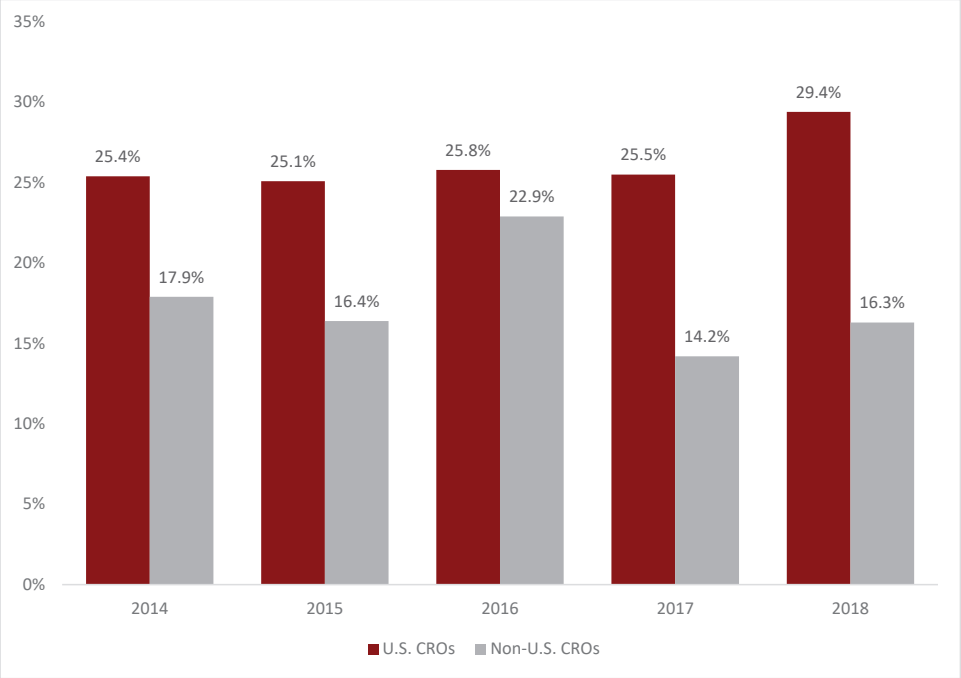
In addition, "high levels of turnover may deter sponsors from engaging in a strategic partnership" with a CRO.

The report points to retention efforts some CROs already are making, such as reducing "travel fatigue" by offering travel perks, creating opportunities to connect with colleagues and accelerating promotions.

Other recommendations for combating employee turnover include instituting merit increases in pay and offering annual performance-based incentives.

"Quite simply, companies need to link the size of the raise to the increase in an employee's contribution," says Judy Canavan, BDO's global employer services managing director.

Average Total Turnover for Clinical Monitoring, 2014-2018



Source: BDO USA

Drug & Device Pipeline News

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
X4 Pharmaceuticals	Mavorixafor in Combination with Ibrutinib	Waldenström's macroglobulinemia	phase 1b clinical trial initiated, enrolling 12 to 18 patients	X4pharma.com
Sol-Gel Technologies	SGT-210	punctate palmoplantar keratoderma type -1	phase 1 proof-of-concept study initiated, enrolling 15 patients	sol-gel.com
BioXcel Therapeutics	BXCL501 (dexmedetomidine)	agitation associated with dementia	phase 1b/2 initiated, enrolling first patient	bioXceltherapeutics.com
Agenus	AGEN1223	cancer	phase 1 trial initiated, dosing first patient	agenusbio.com
InhibRX	INBRX-106	solid tumors	phase 1 trial initiated, dosing first patient	inhibrx.com
Locus Biosciences	LBP-EC01	e. coli bacteria causing urinary tract infections	phase 1b trial opened for enrollment	locus-bio.com
Gemini Therapeutics	GEM103	dry age-related macular degeneration	phase 1 trial initiated, enrolling 9 patients	geminitherapeutics.com
Cytokinetics	CK-3773274 (CK-274)	hypertrophic cardiomyopathy	phase 2 trial opened to enrollment	cytokinetics.com
Protagonist Therapeutics	hepcidin mimetic PTG-300	hereditary hemochromatosis	phase 2 initiated	protagonist-inc.com
CStone Pharmaceuticals Blueprint Medicines	fisogatinib in combination with CS1001	locally advanced or metastatic hepatocellular carcinoma	phase 1b/2 trial's dosing of first patient	cstonepharma.com blueprintmedicines.com
Opthea	OPT-302 administered in combination with aflibercept (Eylea®)	diabetic macular edema	phase 2a trial patient recruitment completed for 108 patients	opthea.com
Galera Therapeutics	avasopasem manganese (GC4419)	radiation-induced esophagitis in patients with lung cancer	phase 2a trial first patient dosed, enrolling 60 patients	galeratx.com
TLC	TLC590	pain management	part 2 of a phase 2 trial dosing first patient of 150 patients	tlcbio.com
PellePharm	patidegib topical gel, 2%,	non-Gorlin High Frequency Basal Cell Carcinoma	phase 2 trial dosing first 2 patients of 40 patients	pellepharm.com
Promethera Biosciences	HepaStem	acute-on-chronic liver failure	phase 2b trial initiated, enrolling 363 patients	promethera.com
Zai Lab Novocure	Tumor Treating Fields in combination with chemotherapy	gastric adenocarcinoma	phase 2 trial, first patient enrolled of 50 patients	zailaboratory.com novocure.com
SELLAS Life Sciences Group	galinpepimut-S	acute myeloid leukemia	phase 3 trial enrolling 116 patients across approximately 50 clinical sites in the U.S. and Europe	sellaslife.com
BioXcel Therapeutics	BXCL501 (dexmedetomidine)	agitation associated with schizophrenia and bipolar disorder	phase 3 trial enrolling up to 750 patients 18 to 75 years of age	bioxceltherapeutics.com
Clover Biopharmaceuticals	SCB-808 (etanercept biosimilar)	ankylosing spondylitis	phase 3 trial enrolling patients at multiple sites in China	cloverbiopharma.com

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Drug & Device Pipeline News

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Company	Drug/Device	Medical Condition	Status	Sponsor Contact
Eli Lilly	LOXO-292 (selpercatinib)	RET-mutant medullary thyroid cancer	phase 3 trial enrolling 400 patients	lilly.com
Mallinckrodt Pharmaceuticals	Acthar Gel (repository corticotropin injection)	severe keratitis	phase 4 trial enrolling 30 patients	mnk.com
Reflow Medical	Temporary Spur Stent System	below-the-knee peripheral artery disease	Breakthrough Device designation granted by the FDA	reflowmedical.com
Savara	Molgradex	autoimmune pulmonary alveolar proteinosis	Breakthrough Therapy designation granted by the FDA	savarapharma.com
Advaxis	ADXS-504	prostate cancer	IND approval granted by the FDA	advaxis.com
OncoImmune	ONC-392	non-small cell lung cancer	IND approval granted by the FDA	oncoimmune.com
Colospan	CG-100 temporary intraluminal bypass device	anastomotic leaks in patients undergoing colorectal surgery	IDE granted by the FDA	colospan.com
Merck	Keytruda (pembrolizumab)	Bacillus Calmette-Guerin -unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ	Approved by the FDA	merck.com
Blueprint Medicines	AYVAKIT (avapritinib)	unresectable or metastatic gastrointestinal stromal tumor	Approved by the FDA	blueprintclinicaltrials.com
Novo Nordisk	Fiasp (insulin aspart injection)	pediatric diabetes	New indication approved by the FDA	novonordisk.com
AstraZeneca Merck	Lynparza (olaparib)	pancreatic cancer	Approved by the FDA	astrazeneca.com merck.com
Myriad Genetics	BRACAnalysis CDx	metastatic pancreatic cancer with a germline BRCA mutation	Approved by the FDA	myriad.com

Research Center Spotlight

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Allergy & Asthma Specialists, P.C.

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aschwartz@allergypc.com

With a database of over 24,000 patients, A&AS consists of twelve physicians. The group has conducted research for 20 years.

Biomedical Research Alliance of New York

Lake Success, NY
516.470.6900
info@brany.com

BRANY offers a turnkey solution for expedited site identification and study startup. Founded in 1998, BRANY now includes over 200 affiliates.

Center for Clinical and Cosmetic Research

Aventura, FL
305.933.6716
info@centerforclinicalandcosmeticresearch.com

With over 50 years of collective clinical research expertise, Drs. Nestor and Berman conduct a variety of FDA and IIS in all areas of Dermatology and Aesthetics. Over 100 studies conducted.

New Orleans Center for Clinical Research/Volunteer Research Group, LLC

Knoxville, TN
865.305.9100 x 246
wbsmd@noccr.com

NOCFCR/VRG is part of AMR. AMR acknowledges the importance of multi-site coordination, allowing it to maximize economies of scale and consistency to exceed Sponsor goals ahead of schedule and under budget.

Oklahoma Heart Hospital Research Foundation

Oklahoma City, OK
405.608.1281
lcordell@okheart.com

Founded in 1993 by a group of cardiologists, OHHRF has conducted 376 studies and has a regulatory turnaround time of five days. OHHRF has 350 active patients in the database, an 81% average percent of total patients randomized and 85% of studies meet enrollment goals.

Paragon Rx Clinical, Inc.

Garden Grove, CA
714.655.5382
caitlynn.musil@prxclinical.com

A dedicated research site with over 20 years of experience conducting Phase I–IV multi-therapeutic clinical trials. Located in the heart of Orange County, CA. Over 50 studies conducted.

Pharmaceutical Research & Consulting, Inc.

Dallas, TX
214.361.5555
emily.osta@daac-prc.com

PRC is a full-time, privately owned clinical research facility. Since 1979, PRC has conducted over 370 Phase II-IV clinical research trials in asthma, allergic rhinitis, bone density, COPD, chronic cough, sinusitis, urticarial, heartburn, bronchitis, allergic conjunctivitis and flu prevention.

Phoenix Medical Research

Peoria, AZ
623.815.9800
research@phxresearch.com

With 20 providers and 6 locations, PMR has been participating in clinical trials since 2008 and has served as an investigative site for more than 40 trials.

Rainier Clinical Research Center, Inc.

Renton, WA
425.251.1720
rcrc@rainier-research.com

Since its establishment in 1991, RCRC has successfully conducted several hundred research studies. The center has a regulatory turnaround time of two weeks.

The Lung Research Center

Chesterfield, MO
314.439.5864
thelungcenter@stlukes-stl.com

The Lung Research Center is a dedicated research center located on the campus of St. Luke's Hospital in Chesterfield, MO. In 20 years, they have conducted 150 clinical trials for the treatment of complex lung disease. They have four certified CRCs and 10,000+ active patients in the database.