Research Projects Show Credentialed Principal Investigators and CRCs Perform Better

By Suz Redfearn

The research is clear: certified principal investigators (PIs) and clinical research coordinators (CRCs) do better work compared with their peers who hold no certification. Much better work, in fact.

That was the thrust of the DIA session Assessing the Impact of Credentialing on Clinical Trial Quality and Performance. It was led by Ken Getz, director of sponsored research programs and associate professor at Tufts Center for the Study of Drug Development, and included the Association for Clinical Research Professionals’ (ACRP) Beth Harper and WCG’s Suzanne Caruso.

“Variance is the enemy of good quality,” said Getz. “There are no real standards or competency requirements for becoming a PI or CRC so the potential for variance in performance is high.”

And the pool of PIs is not stable, which further contributes to the quality problem, he said. In addition, the lack of a structured career path for CRCs and high turnover rates compound the site quality problem, which has devastating consequences for trials, he added.

To offer proper training, ACRP created certification for CRCs, and later, PIs, but neither certification is required to work in the industry. There has historically been much better uptake of the certification for CRCs; about half of all CRCs maintain their certification, which see Principal Investigators on page 4.

Encouraged by Regulators, Sponsors Begin Adopting Real-World Evidence into Clinical Trials

By Michael Bassett

While the FDA is preparing to develop and implement a program evaluating the potential use of real-world evidence (RWE) for regulatory decision making, a panel discussion at this year’s DIA Global annual meeting described how the industry is already using RWE to complement clinical trials.

Tarek Hammad, MD, PhD, head of signal detection and benefit risk assessment, global patient safety innovation at EMD Serono, talked about the role real-world evidence played in the recent approval of avelumab—a PD-L1 monoclonal antibody—to treat metastatic Merkel cell carcinoma (mMCC), a rare aggressive skin cancer.

As explained by Hammad, there is no approved standard of care for treatment of mMCC, so investigators—instead of using a formal comparator arm—generated data from electronic medical records (EMRs) on observed clinical outcomes in a patient population that received chemotherapy in current clinical practice. This data was then used as a benchmark for chemotherapy efficacy in a real-world setting.

The researchers were able to identify a subset of trial patients who responded to treatment with avelumab and document the benefit gained by contrasting it to the benchmarked data. Last year the FDA granted accelerated approval to avelumab. see Real-World Evidence on page 5
Industry Briefs

Gottlieb Says Cancer Drug Surrogate Endpoints Will Be Released for First Time

In the coming weeks, CDER will publish online a list of surrogate endpoints that led to the approval of oncology drugs and biologicals, FDA Commissioner Scott Gottlieb announced at the National Comprehensive Cancer Network Policy Summit in Washington, D.C. “We believe this list will help to address some of the questions that have been raised about how we apply surrogates to make a given regulatory decision,” he said.

“We’ll also be taking steps to provide more guidance to drug developers on these novel approaches.” The guidance will include how to design clinical trials that are based on a biomarker as a novel surrogate endpoint, and the agency will accept sponsor requests for Type C meetings earlier in the drug development process. The meetings can be requested to discuss using a biomarker as a surrogate endpoint in contexts where the marker was never the driving force behind approval. The efforts will give innovators and researchers more clarity about how the agency uses endpoints — and how it expects developers to evaluate biomarkers as surrogate endpoints — in a given disease state, Gottlieb said.

Report Says New Development Innovations Positively Impact Drug Success Factors

A report conducted by the Economist Intelligence Unit (EIU) found that new innovations in drug development positively impact drug development and market access, although the innovations are not yet widely adopted. The report, which was commissioned by PAREXEL, found that the new innovations are not yet widely adopted.

In an effort to provide advice to potential sponsors on critical topics for early drug development, CBER launched its Initial Targeted Engagement for Regulatory Advice on CBER Products (INTERACT) meetings program. INTERACT meetings replace the pre-pre-IND meeting process for all products across CBER. However, they do not replace formal meetings for specific products like pre-IND meetings or pre-BLA meetings that occur in later parts of development. Questions asked during INTERACT meetings should focus on topics related or similar to preclinical testing requirements, aspects of manufacturing required for first-in-human trials, device or assay design considerations and initial clinical development strategies. The advice given by CBER staff to a potential sponsor during an INTERACT meeting could help to streamline the product’s development process. For example, advice provided could help sponsors avoid unneeded clinical studies. The discussions can help to “answer important questions, remove roadblocks and, ultimately, help create a clearer route” toward developing safe and effective products for patients, the center said. CBER plans to post a revised web page describing the meeting program in greater detail in the coming months.

Cel-Sci Wins $3 Million in Arbitration From CRO That Underfilled Phase III Trials

A contract research organization must pay $3 million to Cel-Sci Corp. for underfilling a clinical trial for the drugmaker’s head and neck cancer candidate Multikine (leukocyte interleukin). In its arbitration suit, Cel-Sci claimed inVentiv — now known as Syneos Health — breached its contract with the drugmaker with false enrollment projections. The CRO enrolled fewer than 100 patients during its contract with Cel-Sci, and the drugmaker replaced it in March 2013 with two other CROs, Ergomed and ICON. Under the new CROs, the company successfully enrolled 928 patients in the Phase III study. The arbitrator found material breaches of contract. “We have been vindicated,” Cel-Sci CEO Geert Kersten said in a statement on the ruling, noting the CRO’s actions slowed down the clinical development of the immunotherapy. “The delays in the study caused by inVentiv not only delayed the potential approval of this investigational cancer drug by years, but it caused investors to wonder about the utility of the drug,” Kersten said.
Researchers Find That Compassionate Use Programs Benefit from Clinical Data Right-to-Try May Abridge

The recently-passed Right-to-Try legislation may upset the current balance between investigational new drug access and protection of patients from therapies without established safety, the researchers wrote. “This balance may be compromised by policy makers seeking to speed access to investigational medicines through the Right-to-Try Act.”

Cancer Trials Lack Social Factor Considerations, Johns Hopkins Scientists Say

Social factors like race, ethnicity and economic status should be more regularly taken into account when studying breast cancer risk and treatment outcomes, scientists at the Johns Hopkins Bloomberg School of Public Health say. For example, a 2014 review spanning over 20 years of NCI clinical trials showed that only about 20 percent of the randomized controlled studies stratified results by race or ethnicity. Follow-up analyses of 57 breast cancer observational and randomized controlled trials published in 2016 found that, after excluding trials that focused on disparities, fewer than five percent of them had findings stratified by race or other socioeconomic factors. Commentary by the scientists, which appears in the July edition of the medical journal Cancer Causes & Control, cited evidence that social factors help to determine patient vulnerability to cancer. They argue that the factors should be regularly looked at in studies and clinical risk assessments related to clinical care. “We’ve been missing opportunities to understand and reduce disparities in breast cancer risk and outcomes,” said lead author Lorraine T. Dean, an assistant professor in the Department of Epidemiology at the Bloomberg School. “Simply put, not enough is being done to understand how race, income level and other social factors tie in to cancer susceptibility.”

Synteract Partners With iCAN on Pediatric Research

Synteract announced a collaboration with the International Children’s Advisory Network (iCAN) that will enable the CRO to broaden its access to children and families familiar with clinical research. The network of children’s advisory groups works to give children and parents more input into research, medicine and innovation through education about the role of children’s involvement. Synteract has worked with pediatric clinical trials for the past 30 years and recently named pediatric drug development as one of its primary therapeutic centers of research. “By partnering with iCAN, we gain access to its wide network of children and families spanning socioeconomic, cultural and geographic backgrounds, which will be beneficial for the development of medicines for children,” said Martine Dehlinger-Kremer, Synteract’s head of pediatric development. “Our partnership with iCAN will be valuable in developing better, more appropriate protocols, study designs, patient facing documents and setting strategy for recruitment. It will also help us to further innovation in systems and treatments. It is another important step to show our commitment to this important population.”

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The updated CRA’s Guide covers a wide range of topics to assist CRAs in performing their roles as the industry becomes more global and technologically focused.
Principal Investigators (continued from page 1)

requires that they obtain 24 hours of continuing education credits every two years. Among active PIs, though, as of 2017, only two percent of those working in the field had obtained certification.

Credentialing makes a huge difference in the quality of an investigator’s work.

WCG is working on a study on the topic. Though not complete, the data are already strong. According to Caruso, vice president of clinical solutions for WCG, the majority of ACRP-certified researchers have a low number of protocol deviations. In addition, she said, they have higher enrollment rates across currently active U.S. investigators in WCG’s investigator database, which includes 85 percent of all FDA-regulated investigators and across the company’s site performance data.

Others are studying this issue, too. ACRP has teamed up with the FDA to use FDA inspection outcomes to examine the difference in performance between PIs who have certification versus those who don’t. Thus far, it’s clear that ACRP-certified investigators and coordinators have higher randomization rates and lower numbers of protocol deviations, said Harper, ACRP’s workforce innovation officer. Final results of ACRP’s research on the topic are expected later this summer.

WCG and ACRP are building on research already done by J. M. Hausler in 2009 and David Vulcano in 2012. Hausler performed a retrospective analysis of four trials conducted by a specific sponsor (U.S. multi-center trials) that included 1,400 randomized subjects, which showed that the number of protocol deviations was significantly lower if a PI was certified, and if both a both PI and CRC were certified.

Vulcano — like ACRP is doing now — drilled down on whether there was a difference in FDA inspection outcomes between certified PIs (CPIs) and those who were not certified, and found that CPIs receive fewer for-cause audits, that CPIs are more likely to receive the most favorable outcome and that CPIs are less likely to receive the least favorable outcome.

Explained Harper, the CPI exam is a 100-question multiple-choice test focusing on PI essential duties. To be eligible to take the exam, PIs must have a doctoral degree, show proof of employment as a PI for two years, and across the company’s site performance data. In addition, she said, they have higher enrollment rates across currently active U.S. investigators in WCG’s investigator database, which includes 85 percent of all FDA-regulated investigators and across the company’s site performance data.

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—Ken Getz, director of sponsored research programs, associate professor, Tufts Center for the Study of Drug Development

Other key data from the session:

- Fifty-five percent of the $13 billion the biopharma industry spends annually on clinical trials goes to part-time investigators, while 39 percent goes to academic medical centers and large health systems. Just six percent goes to dedicated sites and site networks.
- Out of 33,920 unique FDA-regulated investigators in 2015 (the most recent year when complete data are available), 64 percent, or 21,570, had only worked on one clinical trial. Turnover rate in this group was 20 percent. Just seven percent (2,491 PIs) had done four to six trials (turnover in that group was five percent) and four percent of the 33,920 (1,213) had done seven or more trials. Among this group, the turnover rate was one percent.
- According to recent data from Tufts, the study initiation (identification through start-up) process takes 36.4 weeks for new sites and 26.2 weeks with repeat sites.

“Site performance is highly unpredictable and expected to be more volatile in the future given growing prevalence of rare and stratified diseases combined with a landscape characterized by fragmentation, low volume, inexperience and turnover,” said Getz, adding that meantime, a growing body of data demonstrates that credentialed site staff perform better in terms of both quality and efficiency measures.

Customizable SOP for Sites

The SOP for the Conduct of Clinical Research has become the industry’s foremost resource for investigative sites seeking to comply with FDA regulations and ICH GCP guidelines.

SOP Highlights include:

- Investigator responsibilities
- Study management materials
- Informed consent requirements
- Human subject protection regulations
- Expectations for medical device trials

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Hammad said that several lessons can be learned from the avelumab approval:

- The use of RWE can be helpful in contextualizing single arm trials for rare diseases, such as mMCC;
- Early planning may be needed if it’s necessary to review patient records or biopsies;
- Response assessment in the real-world setting can be more subjective than those in controlled clinical trials;
- There is always going to be some reporting bias because only patients with complete follow-up information may have been entered into the database, possibly leading to either an under or overestimation of outcome measures;
- Standards of care are rapidly evolving. “So, when new drugs are introduced into a standard of care it’s going to be harder in a real world setting to determine whether the outcome was the effect of particular drug or study or was related to that standard of care, and what new drugs were introduced in that standard of care.”

“With all that said, we are still excited to use real world submissions,” she said, adding that it could help speed up drug development.

Tamy Kim, PharmD, associate director of regulatory affairs, Office of Hematology and Oncology Products at the FDA, noted that the use of RWE must be balanced with several concerns: bias and confounding factors such as different patient characteristics and comorbidities, regional variations in standards of care, the quality and completeness of data, the ways in which physicians assess or diagnose patients and how to deal with data that comes from outside the U.S.

Plus, standards of care are rapidly evolving. “So, when new drugs are introduced into a standard of care it’s going to be harder in a real world setting to determine whether the outcome was the effect of particular drug or study or was related to that standard of care, and what new drugs were introduced in that standard of care.”

“With all that said, we are still excited to use real world submissions,” she said, adding that it could help speed up drug development.

She also observed that that one of the drivers spurring the use of RWE is “that the clinical trial paradigm is a paradigm that is used in a relatively pristine setting,” said Kim.

This means exclusion criteria often leave out certain groups of patients. For example, she pointed out that elderly patients, or patients with brain metastases or poor performance status are often excluded from oncology clinical trials, even though these patients do take oncology products in the real world.

“How do you know when you approve the drug that it’s going to have the same effect in the real world?” she asked. “We’d like to be able to use these drugs in the real world.”

Nancy Dreyer, PhD, chief scientific officer & senior vice president at IQVIA, who moderated the panel, noted that not only is the FDA promoting the use of RWE in clinical trials, but that the European Medicines Agency (EMA) has stated its intent to take an adaptive pathways approach to drug development — which means more use of real-world data.

When it comes to the use of RWE in clinical trials, “the train has left the station” as far as regulators and payers are concerned, said Dreyer.
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## Drug & Device Pipeline News

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<td>ORMD-0801</td>
<td>type 1 diabetes</td>
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<td>Erimos Pharmaceuticals, LLC</td>
<td>terameprocol (EM-1421)</td>
<td>High Grade Glioma (Grade III or IV)</td>
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<td>BioGend Therapeutics</td>
<td>one-step autologous knee cartilage repair/ regeneration</td>
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<td>Phase I trial initiated enrolling 92 subjects</td>
<td>biogend.com.tw</td>
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<td>Rigel Pharmaceuticals, Inc.</td>
<td>R835 (IRAK1/4 inhibitor)</td>
<td>autoimmune and inflammatory diseases</td>
<td>Phase I trial initiated enrolling 91 subjects</td>
<td>rigel.com</td>
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<td>Navitor Pharmaceuticals, Inc.</td>
<td>NV-5138</td>
<td>treatment-resistant depression (TRD)</td>
<td>Phase I trial initiated enrolling 88 subjects</td>
<td>navitorpharma.com</td>
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<td>Axionics Modulation Technologies, Inc.</td>
<td>BA3021 (CAB-ROR2-ADC therapeutic)</td>
<td>advanced solid tumors including non-small cell lung cancer (NSCLC), triple negative breast cancer and soft tissue sarcoma</td>
<td>Phase I/II trial initiated</td>
<td>bioatla.com</td>
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<td>Roche and Genentech</td>
<td>TECENTRIQ (atezolizumab) plus chemotherapy (carboplatin and etoposide)</td>
<td>Extensive-stage small cell lung cancer (ES-SCLC)</td>
<td>Phase III trial initiated enrolling 403 subjects in the U.S.</td>
<td>roche.com gene.com</td>
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<td>Beckman Coulter Diagnostics</td>
<td>Access hsTnl (high-sensitivity troponin assay)</td>
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<td>Renovis Surgical Technologies, Inc.</td>
<td>Tesera SA Hyperlordotic ALIF Interbody Spinal Fusion System</td>
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<td>Genentech</td>
<td>Baloxavir marboxil</td>
<td>single-dose oral flu treatment for people 12 years and older</td>
<td>Priority Review and NDA approval granted by the FDA</td>
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<td>Merck &amp; Company</td>
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<td>Glaukos Corporation</td>
<td>iStent inject Trabeular Micro-Bypass System</td>
<td>reduction of intraocular pressure (IOP) in adult mild-to-moderate primary open-angle glaucoma (POAG) patients undergoing concomitant cataract surgery</td>
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<td>Ferring Pharmaceuticals Inc.</td>
<td>NOCDURNA (desmopressin acetate)</td>
<td>treatment of nocturne due to nocturnal polyuria in adults who awaken at least two times per night to void</td>
<td>Approval granted by the FDA</td>
<td>ferringUSA.com</td>
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<td>Achaogen</td>
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<td>Array BioPharma, Inc.</td>
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<td>Processa Pharmaceuticals, Inc.</td>
<td>PCS499</td>
<td>Necrobiosis Lipoidica (NL)</td>
<td>Orphan Drug Designation granted by the FDA</td>
<td>processapharma.com</td>
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For news on trial results, FDA approvals and drugs in development, Join the LinkedIn Drug Research Updates group!
Navitor Pharmaceuticals Initiates Phase I Trial of NV-5138

Navitor Pharmaceuticals announced the initiation of a Phase I clinical study with its lead pipeline candidate, NV-5138, for treatment-resistant depression (TRD). NV-5138 is a novel small molecule that directly activates mTORC1, a master cellular regulator that has recently been shown to be a central signaling pathway required for the efficacy of several rapid acting antidepressants. NV-5138 is initially being evaluated in TRD but may offer future potential for the treatment in the broader disease category of major depressive disorder (MDD). The Phase I, multicenter, two-part, double-blind, placebo-controlled study will evaluate the safety, tolerability and pharmacokinetics of NV-5138 in up to 88 subjects, including healthy volunteers and patients diagnosed with TRD. In Part A, the single-ascending-dose portion of the study, up to 48 healthy volunteers will be randomly assigned to double-blind treatment in six dosage-level cohorts. Within each cohort, six subjects will be randomized to receive NV-5138 and two subjects will be randomized to receive placebo. In Part B of the study, approximately 40 subjects diagnosed with TRD will be randomly assigned to double-blind treatment at a single dosage level that will be established based on data from Part A of the study.

Amgen Announces Top-Line Results From Phase III Study

Amgen announced results from a Phase III study evaluating the efficacy and safety of biosimilar candidate ABP 710 compared with REMICADE (infliximab) in patients with moderate-to-severe rheumatoid arthritis. The results confirm non-inferiority compared to infliximab but could not rule out superiority based on its primary efficacy endpoint, which compared the response difference measured by 20 percent or greater improvement at week 22. Key secondary endpoints included ACR50, ACR70 and Disease Activity Score 28-joint count C reactive protein (DAS28-CRP). The primary endpoint of ACR20 had a prespecified equivalence margin of +/- 15 percent, and the observed upper end of the confidence interval was 15.96 percent. The Phase III study was a randomized, double-blind trial. There were 558 patients enrolled and randomized (1:1) to receive either ABP 710 or infliximab at a dose of 3 mg/kg administered as an infusion on day 1, at weeks 2 and 6, and every 8 weeks thereafter. Among them, 279 patients were randomized to the ABP 710 group and 279 patients were randomized to the infliximab group. The primary endpoint was assessment of ACR20 at week 22. Key secondary endpoints included ACR50, ACR70 and the DAS28-CRP.

GBT Announces Positive Top-line Data from Phase III HOPE Study

Global Blood Therapeutics announced the completion of a planned review of Part A of the Phase III HOPE (Hemoglobin Oxygen Affinity Modulation to Inhibit HbS PolymErization) Study, which is evaluating voxelotor for the treatment of sickle cell disease (SCD). On the primary endpoint (the proportion of patients with greater than 1 g/dL increase in hemoglobin versus baseline), a statistically significant increase was demonstrated with voxelotor at both the 1500 mg and 900 mg doses after 12 weeks of treatment versus placebo. The HOPE Study is a randomized, double-blind, placebo-controlled, multinational study that enrolled patients age 12 and older with SCD who had had at least one episode of VOC in the previous year. The study was originally designed in two parts: Part A compared voxelotor administered at doses of 900 or 1500 mg per day versus placebo in 154 patients treated for at least 12 weeks, and Part B planned to enroll 250 patients randomized to placebo or a dose of voxelotor selected from Part A. The primary efficacy endpoint is the proportion of patients who achieve a greater than 1 g/dL increase in hemoglobin at 24 weeks of treatment compared with baseline. Key secondary efficacy endpoints evaluated in Part A were the effect of voxelotor on SCD symptom exacerbation as measured by the PRO instrument, overall SCD symptoms as measured by the PRO instrument, and traditionally defined VOCs. The study found 58 percent of patients taking the 1500 mg dose (p<0.0001) and 38 percent of patients taking the 900 mg dose (p=0.0021) achieved a greater than 1 g/dL increase in hemoglobin at 12 weeks versus 9 percent of patients taking placebo. This compares favorably to the hemoglobin increase assumption agreed to with the U.S. Food and Drug Administration (FDA) in the HOPE Study protocol of a 35 percent response.

BioAtla Announces First Patient Treated In Phase I/II

BioAtla announced the treatment of the first patient in its clinical trial BA3021-001 for BioAtla’s BA3021, a novel conditionally active ROR2-targeted antibody-drug conjugate (CAB-ROR2-ADC). This is a multi-center, open-label, Phase I/II study designed to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and antitumor activity of BA3021 in patients with advanced solid tumors including non-small cell lung cancer (NSCLC), triple negative breast cancer and soft tissue sarcoma. The CAB-ROR2-ADC BA3021 is designed to maximize efficacy on ROR2 expressing tumors while minimizing toxicity, leading to better clinical outcomes. The ROR2 transmembrane protein tyrosine kinase is an onco-fetal protein that acts as a non-canonical Wnt 5A receptor. ROR2 is found to be highly expressed during embryonic development and in several important cancer types, and the level of expression in tumors is tightly correlated with patient prognosis.
Upcoming Event Highlights

**Conferences**

- **AUGUST 8-10, 2018**
  - FDAnews — ICH E6 GCP Interactive Workshop
    - Waltham, MA

- **SEPTEMBER 10-12, 2018**
  - Mastering EU Medical Device Regulation
    - Philadelphia, PA

**Training Programs**

- **AUGUST 1-31, 2018**
  - Program Phlebotomy Training — Two Day Training
    - Various locations

**Webinars**

- **JULY 11, 2018**
  - Preparing for the MDSAP Audit Process: A Case Study from the Manufacturer’s Perspective
    - Consultant Connie Hoy takes you through the changes — what’s the same, what’s different about the audit and inspection process as the new Medical Device Single Audit Program (MSDAP).

- **JULY 17, 2018**
  - Real-World Evidence Evaluating Benefit & Risk: What Device makers Need to Know
    - NEST is seen as a real opportunity to find “better, faster, cheaper” approaches to evidence-based generation for device evaluation ... and get your new products to market and to patients in less time.

Jobs via Kelly Services

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Academic Programs

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

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

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