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The Clinical Coordinator

Clinical Research News You Can Use

INSIDE THIS ISSUE

Public Shaming Continues for Late ClinicalTrials.gov Results

Over the past few years, there has been a steady stream of reports that expose and shame researchers and institutions for submitting results late (or not at all) to ClinicalTrials.gov. The latest articles came out last week in the journals *Science* (at this link) and *The Lancet* (at this link). Both articles are based on data obtained from the high-profile public shaming site TrialsTracker (at this link), which identifies studies for which results are not reported on time.

Performance of UTHealth and Other TMC Institutions

A chart in the *Science* article displays the performance of US institutions that have registered 15 or greater PI-initiated drug or device trials with a results due date between January 2018 and September 2019. UTHealth and other TMC institutions are included in the chart, and particularly poor performers from across the US are named in the article. UTHealth's position near the top of the chart indicates that UTHealth has registered more studies than some larger research programs and also suggests that UTHealth has good compliance in terms of the registration requirements of the law. As for compliance with the results reporting requirements, this report reflects relatively well on UTHealth, as results for 24 out of 29 of UTHealth's studies were reported on time. Though, results for 5 UTHealth studies were not.

FDA and NIH are Called Out

The *Science* and *The Lancet* reports fault investigators and institutions but also FDA and NIH for failing to crack down. We can expect the public shaming to continue until compliance improves and/or regulators take action, and the intended effect of this shaming is to push FDA to penalize via fines and NIH via consequences to grant funding.

Know Your Results Due Date

Results are due to ClinicalTrials.gov one year after the "Primary Completion Date," which is defined as the date that the last piece of data contributing to the primary outcome is collected. Note that even if you enrolled only one or two patients, prematurely stopped the study, and/or have no plans to analyze the data, you are still required by law to enter the data to ClinicalTrials.gov by the legal due date.

How Study Teams Can Avoid Public Shaming

As soon as the Primary Completion Date is reached, update the Study Status section of the ClinicalTrials.gov record and notify UTHealth's ClinicalTrials.gov results administrator, Elizabeth Gendel. Elizabeth contacts study teams in advance of the results due date and works closely with teams to enter results on time; however, in order for her to know the results due date, Elizabeth is reliant on the study team to keep the primary completion date updated in the ClinicalTrials.gov record.

Work With Elizabeth Gendel to Enter Results

You will need to work closely with Elizabeth Gendel during the results entry process, for a couple of reasons:

- First, the full, IRB-approved protocol document must be uploaded to ClinicalTrials.gov at the

time of results entry, and this protocol will be publicly displayed for all to see. Before upload of the protocol to ClinicalTrials.gov, the protocol must be reviewed for any personally identifiable, trade secret, or confidential commercial information, all of which will need to be redacted from the protocol—Elizabeth will coordinate this review and will lead you through the legally required methods for redaction and preparation of the file for upload.

- Second, the results entry process is more complicated than registration and is not intuitive; therefore, we highly recommended that you work closely with Elizabeth to enter results to ClinicaTrials.gov.

For assistance, contact Elizabeth Gendel, PhD at 713-500-3587 or Elizabeth.M.Gendel@uth.tmc.edu.

Christian Urbina Joins GI Hepatology

We are pleased to welcome **Christian Urbina, BS** to the Internal Medicine Gastroenterology (GI) and Hepatology Research team. Christian will work as a research coordinator for the department GI and Hepatology. He earned a Bachelor of Science degree in Biological Science from the University of Notre Dame and has previous experience working in research, as he worked for the Pediatrics department for almost 3 years. Welcome to the team, Christian—we wish you good luck!

Angelica Rodriguez Joins Hematology

We are happy to announce that **Angelica Rodriguez, BA, MS** joined UTHealth in October of 2019 s a Research Coordinator II in the Internal Medicine department. Angelica has earned a Bachelor of Arts in Psychology from Texas State Universality. She then went on to earn a Master of Science in Psychological Sciences from the University of Texas at Dallas. She is also a Delta Gamma fraternity Alumna with the Zeta Eta Chapter. Angelica will be working as Dr. Idowu's research coordinator in research involving Sickle Cell Anemia. Welcome, Angelica, we wish you all the best!

Test Your Good Clinical Practice Knowledge

1. A _____ is an individual designated by a sponsor or contract research organization to oversee the progress of an investigation.

2. An auditor is usually independent of the study. TRUE or FALSE?

3. Monitoring is necessary to assure that the rights and safety of patients are protected. TRUE or FALSE?

4. When a specific, original record cannot be made available for monitors/auditors, a certified copy of the original record maybe used. TRUE or FALSE?

Answers:
1. monitor, 2. true, 3. true, 4. true

Alba Zeigler Joins CPHS as Coordinator of Panel 1

We are happy to announce **that Alba Zeigler, BS, CPhT** joined UTHealth's Committee for the Protection of Human Subjects (CPHS) on December 09, 2019, and she will serve as IRB Coordinator for Panel #1. Alba will be responsible for providing guidance and administrative support to investigators regarding protocol submissions for Institutional Review Board (IRB) consideration. Her previous employment was with M.D. Anderson Cancer Center (MDACC), where she worked as a Research Data Coordinator for the last 2 ½ years in the Genomic Medicine Department. Her role at MDACC consisted mainly of ensuring high quality data management and screening for eligible participants to facilitate enrollment. Additionally, Alba worked in MDACC's Outpatient Pharmacy from 2007 to 2013, until she left to finish her Bachelor's degree. Alba earned a B.S. in Biological & Physical Sciences from UH- Downtown. She's a nationally certified Pharmacy Technician (CPhT), was in the military (NAVY) for 4 years (1999 to 2003), and is currently enrolled in the UTHealth Clinical Research Curriculum program, with the goal of achieving Clinical Research Coordinator Certification in the next 2 years. Welcome, Alba—we're so happy you're here!

Jessica Martinez Accepts New Role in CTRC

We are pleased to announce that **Jessica Martinez, BS** has accepted a full-time position within the Clinical Trials Resource Center (CTRC). Jessica previously served as a Graduate Assistant within CTRC, and in December, she joined as a Research Assistant. In her current role, Jessica will assist in quality assurance reviews, as well as IND and IDE applications. Jessica earned a Bachelor of Science in Mathematics from the University of Houston, and she's currently a graduate student in biostatistics at UTHealth's School of Public Health. We're so happy to have you as a part of the team, Jessica, and we look forward to working with you!

Renu Abraham Joins Office of Conflict of Interest and CTRC

Renu Abraham, BS, MSHA, MBA has joined the team as a Research Compliance Specialist and will be working with both the Office of Conflict of Interest and the Clinical Trials Resource Center. Renu grew up in Maryland, and after getting married, she moved to Texas in 2016. She previously worked as a Research Data Coordinator at the MD Anderson Cancer Center. Prior to that, she worked as a contractor for the National Institutes of Health, with the Division of AIDS, where she worked on clinical research site pharmacy implementation and oversight. Renu earned her Bachelor of Science in Biology from Howard University and later completed her Master of Science in Healthcare Administration and Master of Business at the University of Maryland Global Campus. Welcome, Renu—we're so happy that you're here and a part of the team!

Upcoming Training

iRIS Training

Objective: Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHealth's CPHS and AWC.
Date and Time: January 8, 2020; January 30, 2020
Time: 1:30 pm - 4:00 pm
Location: 1/8 at UCT 1155, 1/30 at UCT 1160 (parking will be validated)
Registration is required. Register here.

Study Coordinator Monthly Forum

Objective: Discuss best practices in clinical research management. More information here.
Date: February 26, 2020
Time: 11:30 am – 1:00 pm
Topic: Mock Consent Presentation
Location: MSB 3.001 (*Note the different location for February*)
Lunch will be provided for the first 40 participants. Registration is not required.

TMC – SoCRA METS

Objective: Monthly training and educational event for clinical research professionals.
Date: February 5, 2020
Time: 3:30 pm – 4:30 pm
Topic: "Expanded Access Program/Pathway/Process (EAP)" by Patricia A. Mendoza, BA, BSN, RN, CCRC, CHRC, CCRP, Houston Methodist Hospital
Location: Third Coast Restaurant, 6th floor room II, 6550 Bertner Avenue
Registration is required. Register here.

SOCRA CCRP Prep Course

Date: January 30, 2020
Time: 8:00 am – 4:00 pm
Topic: Clinical research professional certification preparation and GCP review course
Location: MD Anderson Cancer Center
Registration is required. There is a fee for the course. Register here.

IRB Office Hours

If you would like help submitting an iRIS application or writing a protocol or consent form, or if you want to learn more about IRB reciprocity agreements, then consider taking advantage of IRB office hours.
MSB hours: 2nd and 4th Thursdays from 1:00 pm – 4:00 pm at MSB B.640
SOD hours: 1st Thursdays from 1:00 pm – 4:00 pm at SOD 4416 (Research Office conference room).
An appointment is not necessary

About the Clinical Trials Resource Center

It is the mission of the Clinical Trials Resource Center (CTRC) to provide a single portal of expertise and best practices for study teams in order to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT suite 1840. Please visit https://www.uth.edu/ctrc/ for more information.

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We would love to hear from you.
Please send your comments and suggestions to clinicaltrials@uth.tmc.edu.