Issue 10 | Summer 2020

TriNetX

IN THIS ISSUE …

Welcome to our New Members!

New HCOs:
- Arkansas Children's Hospital, *AR, USA*
- Centro Medico ImagenSalud – IS, *Chile*
- Instituto de Diabetes Obesidad y Nutrición, *Mexico*
- JSC Saules Seimos Medicinos Centras, *Lithuania*
- Mediclinic Middle East, *United Arab Emirates*
- Medisprof Cancer Center, *Romania*
- University Hospital Schleswig-Holstein, *Germany*
- University of Maryland, Baltimore, *MD, USA*
- Vanderbilt University Medical Center, *TN, USA*
- Wojewódzki Szpital Specjalistyczny we Wrocławiu, *Poland*

Newly Activated HCOs:
- Anne Arundel Medical Center, *MD, USA*
- Grand Hôpital de Charleroi, *Belgium*
- INOVA HealthCare Services, *VA, USA*
- Royal Liverpool and Broadgreen University, *UK*

Letter from Brecht Claerhout, Chief Data Officer

Welcome to the summer edition of our newsletter. We hope that you and your loved ones are healthy and that you can look forward to, or back on some well-deserved time off.

As the pandemic rages on, we are proud to be part of a select group of companies that manages to maintain growth in all areas during this challenging time.

On the data front, our partnerships and associated networks continue to expand at pace. In the first half of 2020, an additional 20 Healthcare Organizations (HCOs) went live on networks across 8 countries. TriNetX signed 21 new HCOs and data partnerships across 12 countries, including our firsts in Canada, Mexico, Romania, Taiwan, and the United Arab Emirates. A little over one year post merger, more than 50% of the European partners of the InSite network have now signed up to convert to the TriNetX network.

Maintaining a leading position requires one to constantly evaluate and fine-tune one's organization. As part of this process, in the past months we have centralized all data acquisition, implementation and expansion teams into one department, responsible for the creation and execution of our data strategy.

Moving forward, this will allow us to better align the expansion of our data asset with the different needs of our customers, maximizing the value that our platform brings to the R&D and post-approval space. We remain committed to building a unique global data offering and aim to accelerate our ex-US presence by strengthening our teams both in Europe (France) and the Asia-Pacific region (Japan) before the end of the year.

Finally, as part of our ongoing commitment to fight COVID-19 with data (e.g., with the establishment of the COVID-19 Rapid Response Network), we are building a clinically enriched dataset through a retrospective medical record review of US COVID-19 patients in order to support treatment and vaccine research. As part of our quest for deeper data, TriNetX's chart review processes leverage our close relationship with HCOs and advanced technology, to efficiently build comprehensive, in-depth, regulatory-grade datasets.

We hope that you enjoy this newsletter, and please continue to stay safe!

Brecht

Brecht Claerhout
Chief Data Officer

TriNetX Helps Customers Gain Deeper Clinical Insights Through Medical Record Review

Pamela Landsman-Blumberg, MPH, DrPH, *Vice President, Value and Access, TriNetX*

TriNetX was first to market with a de-identified research ready US COVID-19 electronic medical record (EMR) database, a subset of the Dataworks Network. To date, ten COVID-related studies using this data have appeared in peer-reviewed scientific publications authored by HCOs contributing data to this network and pharmaceutical industry researchers. TriNetX is now building on the usefulness and success of this offering by conducting a retrospective medical record review of 200 laboratory confirmed, hospitalized COVID patients. The design allows for the capture of deeper clinical detail regarding a patient's treatment journey than what is accessible in standardized EMR data available in products like Dataworks. The end-product will be a clinically enriched regulatory-grade dataset designed to be complementary to the EMR database and will further support COVID-19 drug treatment and vaccine research.

COVID patients treated at four geographically dispersed HCOs within the TriNetX USA Network will be randomly identified with the record abstraction conducted by the sites' staff. Over 100 data elements including laboratory test results, ICU stay detail, mechanical ventilation/ECMO utilization, and drug treatments received will be captured. The first record abstraction is expected this month–the project will then be completed, and the database will be available in Q4 of this year.

This effort is part of a new TriNetX medical record review study offering. Study designs can be retrospective or prospective but must be observational as opposed to interventional. They are appropriate for any disease or therapeutic area where the data required can only be found in the physician notes or other documents stored within the medical record. In addition, with the exception of the U.S., access to data for industry sponsored research is limited outside of clinical trials. With HCOs now in 28 countries and expanding, TriNetX is uniquely positioned to undertake these studies on behalf of and in collaboration with pharmaceutical and biotechnology company sponsors. If you would like to learn more about the COVID-19 medical record review project specifically, or how medical record reviews can help meet your research objectives, please send an email to join@trinetx.com.

Industry Spotlight

Inspired by patients. Driven by science.

UCB is a global biopharmaceutical company with a team of approximately 7,500 employees and operations in more than 40 countries. UCB's global headquarters are in Brussels, Belgium, with U.S. headquarters in Atlanta, Georgia. Additional U.S. UCB sites include global clinical development in Raleigh, North Carolina, and research supporting UCB's pipeline in Boston, Massachusetts, Seattle, Washington and Durham, North Carolina and offices in Washington, D.C..

At the core of the business is the simple question: how will this create value for people living with severe disease? UCB's business – from discovery to development to delivery – is redesigned around the patient's individual experience as patients are at the heart of everything they do, inspiring them and driving scientific discovery. For information on UCB's disease areas and pipeline, please visit **www.ucb-usa.com/Innovation/Pipeline**.

Expanding the TriNetX Network: How You Can Help

Laura Meloni, *Director, Data Networks, Europe South, TriNetX*

The success of the global TriNetX network comes from the enthusiasm of partners in clinical research, with HCOs making information available about the patients they treat in order to attract the best clinical trials, and industry partners analyzing this data to design more relevant studies, place trials at the right sites, and find the patients that best fit study criteria as quickly as possible.

This strategy has been very successful so far, but the expansion of our network goes beyond that. To further increase the value of our network, TriNetX is eager to leverage the existing relationships that our industry partners have with key principal investigators and sites all over the world in order to engage and approach preferred sites together to establish connections. Through this process, introductions will be made to HCOs, which will in turn highlight the benefits of participating in the network from both points of view. Connecting your favorite site to our network will open up the potential for more clinical trials to be held at such organizations. We are also happy to introduce you to principal investigators at our partner hospitals, as they are very eager to increase their visibility towards sponsors and are looking to strengthen their collaborations with you. The final goal is to further expand the potential of clinical sites in our partner organizations from both sides. TriNetX is excited to introduce sponsors to our partner hospitals so that we can support you in forging new alliances with sites that are keen to host more clinical trials. TriNetX is of course also happy to support hospitals that are maximizing their relationships with our partner industries in order to optimize the re-use of their EMR data in the different stages of the clinical trial process.

To facilitate this collaboration, we invite you to contact your TriNetX account manager in order to discuss how to include your preferred sites in the TriNetX network, or reach out to the hospital engagement team to put you in contact with the right people within the pharmaceutical organizations to strengthen your relationships.

Trial Connect Best Practices

Paula Underhill, ***Director, Global Clinical Engagement, TriNetX***

Trial Connect enables our industry partners to easily identify patient cohorts for query, protocol development, chart reviews and quickly identify potential HCOs, based upon patient availability, to participate in clinical trials; proactively streamlining communication between our HCOs and pharma/CRO customers. For our HCOs, Trial Connect proactively supports and enhances their commercial portfolio growth, using their data in an efficient, compliant and evidence-based manner to increase and broaden their participation in research; ultimately to meet the clinical and changing needs of their patients and local populations.

An example of one of our many Trial Connect successes has arisen recently, relating to a pharma customer, who utilized the functionality to engage with a number of HCOs, for a Phase II COVID study; receiving their first response within 7 minutes (compared to the industry average of 42 days) with 19% of sites contracted to-date expressing an interest.

The overall positive impact of Trial Connect is largely predicated based upon the transparency of sharing of information between the requesting industry partner and the receiving HCO. Success can also be further cultivated by leveraging our HCO and industry account managers, and their relationships, to further enhance and broaden its utilization and wider benefits.

Trial Connect is one of the most powerful and strategic features within the platform and therefore capitalizing on its potential to all parties is pivotal to its continued success by: continually sharing best practices; developing and facilitating bespoke training for the needs of our users; maintaining a clear understanding and knowledge of internal processes affecting utilization within an organization to ensure requests are dealt with responsively and informatively.

Areas where TriNetX can further support and foster by:

- Driving commercial portfolio growth to ALL of our global HCOs; promoting and understanding regional/HCO capabilities, strengths, and potential challenges to overcome. Synergy between all of our teams will ensure greater insight into our global network of HCOs and their unique abilities for undertaking research across therapeutic areas as well as knowledge of specialist providers of healthcare.
- Working with our HCOs proactively to understand any barriers/challenges causing a trend for declining opportunities and/or non-responses and provide root cause analyses of such trends to support improvement.
- Working with our industry partners to ensure that their understanding and education of Trial Connect is comprehensive, undertaken with the right team(s) and offers robust root cause analyses of issues relating to poor responses.
- Continuously reviewing our Trial Connect training and tools supporting wider understanding and utilization to suit the needs of a range of users across HCOs and industry.
- Expanding awareness of Trial Connect to all users and crucially, the potential for its wider use: such as seeking early engagement/collaboration, clinical feedback on specific therapeutic areas/pathways and a mechanism to add supporting information, from the platform (such as rate of arrival) to improve site selection for HCOs.
- Promoting the dedicated support for site intelligence, identification and specific questions relating to potential study set up, delivery and recruitment where relevant, prior to triggering a formal Trial Connect request.

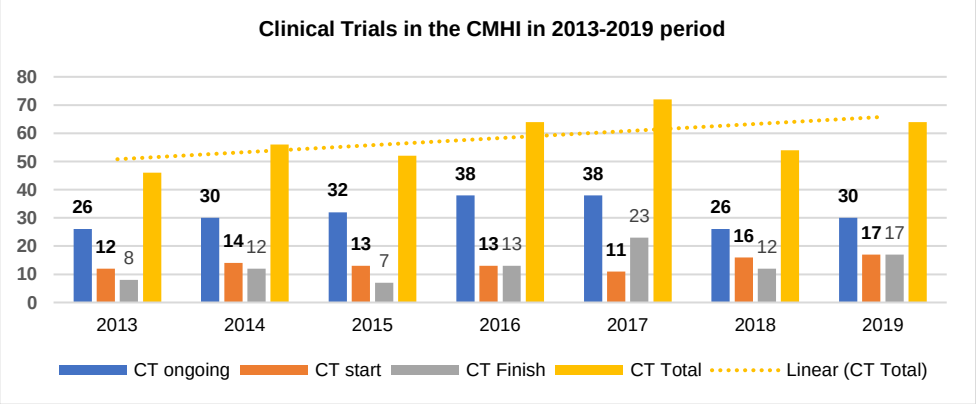
Part of my new role as Director of Global Clinical Engagement, is to work with our industry sponsors and HCOs to broaden and strengthen the global utilization, efficacy and performance of Trial Connect (regardless of whether facilitated via the platform or a manual concierge service), and I look forward to working with you all to help achieve this goal.

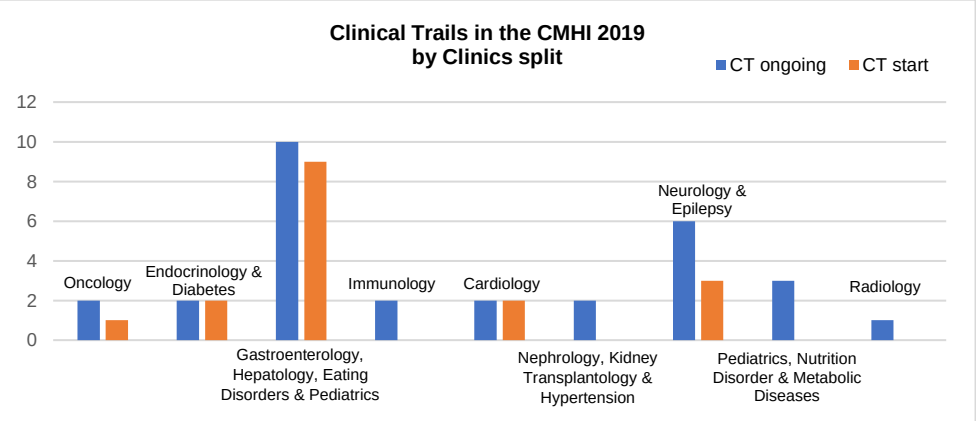
I would welcome any comments you have and as such, please do not hesitate to contact me at Paula.Underhill@TriNetX.com.

EU HCO Spotlight: Centrum Zdrowia Dziecka – The Children's Memorial Health Institute

Dorota Gągała, *Clinical Trials Service Specialist, The Children's Memorial Health Institute*

The Children's Memorial Health Institute (The CMHI) is the largest pediatric hospital in Poland and Europe (596 beds). It is also a research institute (with the highest scientific category level – A+) conducting medical activity on which the research activity is based. Every year, a quarter of a million children from all over Poland are treated at the CMHI. The conducting of clinical and observational trials are included in the statute of the CMHI as well. In 2019, the CMHI conducted 64 clinical trials, commenced on 17, continued 30 and completed 17.





The CMHI has been participating in national and international projects for many years. Thanks to participation in all EU projects dedicated to clinical trials in pediatrics (GRIP, SMART, ID-EPTRI, c4c), the CMHI gained valuable experience and knowledge on designing and conducting clinical trials using its human and scientific potential for subsequent research projects. Since 2017, the CMHI has been the coordinator of the Polish Clinical Research Network in Pediatrics (POLPEDNET), consisting of 9 pediatric centers in Poland experienced in conducting clinical trials (ca. 3000 beds).

Through c4c, the CMHI cooperates with 19 European networks of clinical trials in pediatrics, as well as specialized institutions such as ECRIN, CBVF, BBMRI. The CMHI representatives take an active part in the work of the Pediatric Committee of the European Medicines Agency (EMA), the Orphan Medicines Committee of the EMA, the European Network of Clinical Trials in Pediatrics at the EMA (EnprEMA) and EJP RD. The CMHI is a member of two ERNs and was positively accepted by the Ministry of Health for another six ERNs. The possibility of European influence also increases its active membership of the European Pediatric Hospitals Network (ECHO).

Through collaboration with the TriNetX platform, the CMHI plans to actively initiate clinical projects using new directions of clinical trial development (e.g., modeling and simulation, development of disease registries) in order to become an incubator of ideas and optimally use its human and equipment resources. These activities will guarantee the increase of the pediatric clinical trials' number and will contribute to the fulfillment of the mission of the CMHI: "We provide treatment at the highest level. The most important thing is the CHILD."

US HCO Spotlight: Stony Brook University

Matt Skowronek, *Customer Success Manager, TriNetX*

Stony Brook University/Stony Brook Medicine boasts 4 hospitals, 94 satellite locations and in 2019, had 1.6 million patient visits. As an academic medical center, they utilize the TriNetX platform not only for their established researchers, but also as a valuable tool for graduate students working with biomedical data. When they began their TriNetX journey in 2018, they were only utilizing Trial Connect, however, they have since expanded to now routinely use Export ID to aid in study recruitment and to quickly identify subjects' MRNs for retrospective chart reviews, and their researchers are also now digging into the Analytics platform for cohort research and Treatment Pathways.

With the onset of the COVID-19 pandemic, Stony Brook was thrust into the midst of the virus, being located on Long Island, NY, which has pushed them to use TriNetX for its best use: research and cohort identification. With data coming directly from their EMR, Natural Language Processing (NLP), Patient Linking, Genomics and Cancer Registry, Stony Brook had all the data needed to begin COVID-19 research. Stony Brook is also one of our HCOs partnering to upload their COVID-19 data to the National COVID Cohort Collaborative (N3C). Stony Brook Medicine holds data in a very high regard and performs internal quality assurance via their biomedical informatics department on the data that they upload to TriNetX to ensure the best quality data. They compare Stony Brook data in TriNetX to their internal reporting to guarantee the correctness and fullness of the data available. For example, one of these QA checks was performed when they compared their mandatory disease reporting for incidences of whooping cough to those positive lab values for pertussis in TriNetX during the same time period.

Through all of this, Stony Brook also began a University-wide rollout of TriNetX to their researchers, utilizing all of the training materials that TriNetX has available within the platform, weekly training sessions for researchers, and an amazing TriNetX-specific website that provides all of the information one would need to get started with TriNetX (**www.stonybrookmedicine.com/trinetx**).

Along with their abundance of data, excellent Trial Connect processes and availability to researchers, the Stony Brook team has also leveraged the TriNetX Clinical Sciences team and the Design Assistance feature in order to help their researchers obtain more complete and robust query results. Looking forward, Stony Brook is most excited about using TriNetX to see health trends, to better understand viable treatment pathways, and to use such data in order to continue serving their community of patients and helping them live healthful lives.

If you would like to learn more about Stony Brook University/Stony Brook Medicine, discuss forming a Collaborative Network with them, and/or learn more about partnering with TriNetX to contribute data to N3C, please contact the TriNetX Clinical Account Management team at **collaboration@trinetx.com**.

TriNetX Platform Update – What's New to TriNetX?

We've made some exciting improvements to the TriNetX platform in the past quarter. Read on for information about what's new…

Including Onboarding Sites in Trial Connect Requests

Many HCOs – including those in Europe, Brazil, and the Asia-Pacific region – are in the process of setting up their data syncs with TriNetX. We refer to these HCOs as "onboarding." Now you can include these HCOs in your list of Trial Connect recipients.

You will find onboarding HCOs listed in the cohort counts provided on the HCOs page. For more details, check out the article, "*Include Onboarding Sites in your Trial Connect Request*" in the Resources: Product Release Announcements section of our Help Center.

Updates to Trial Connect Workflow

Trial Connect improves the efficiency with which study sponsors, CROs, and HCOs find collaborators for clinical trials. Over the last couple of years, our community's experience with Trial Connect has revealed an important lesson: the process works most efficiently when requestors and recipients share information with transparency and detail.

To make sure that happens, we have updated the Trial Connect request form, email, and dashboard. Read about these enhancements in the article, "*Update to Trial Connect Request Form*" in the Resources: Product Release Announcements section of our Help Center.

Import Queries

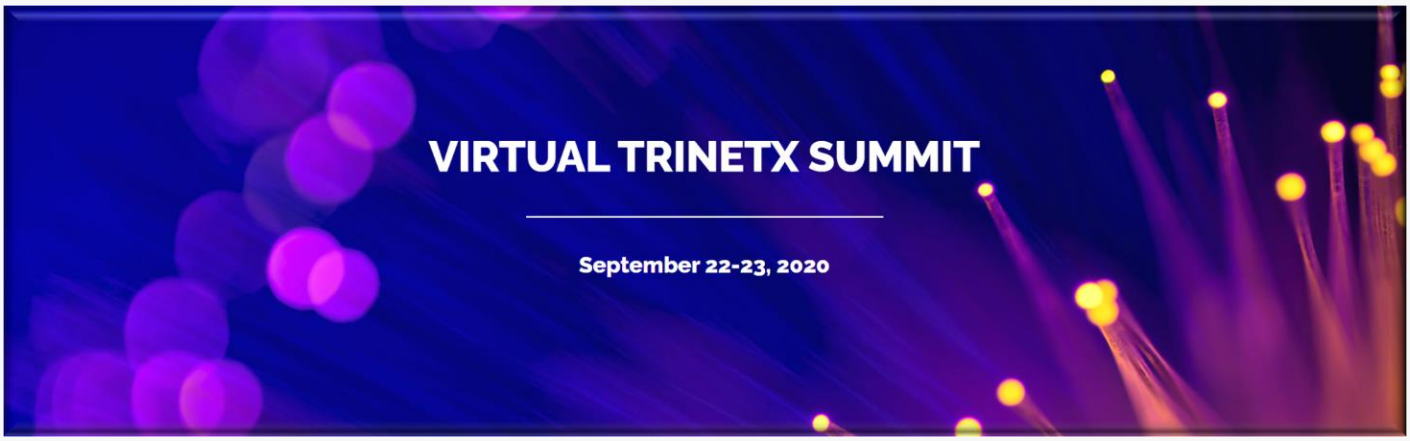
You can now import queries from other studies to save time finding terms and building logic. The process is easy. Before adding any term to a new query, first select the *Import Query* button that appears in the middle of Query Builder. A pop-up menu will present the list of studies shared with you. Select the study that contains the query that you want to import, then scroll or search for that query. Select import to reproduce all of the terms and logic of the source query into your new query.

COMING SOON: Study Purpose

The HCOs who supply data to the TriNetX platform do so under the legal justification that this data will be used for research, in compliance with regulatory requirements. They have a responsibility to show to regulators, internal policymakers, and patients that their contribution to the TriNetX platform complies with this acceptable use.

To help TriNetX member organizations demonstrate their compliance, we ask for Research Purpose whenever you create a study. This practice not only helps the HCOs in our network fulfill a regulatory requirement, but it also builds trust across our community, allowing us to grow the volume of international data on our platform.

Please visit our Help Center to stay informed regarding new and forthcoming features!



Where Healthcare Organizations and Industry Discuss the Future of Clinical Research

Save the date for the 2020 TriNetX user conference held September 22nd and 23rd online. The two-day event will bring the global community of TriNetX members together to network, share best practices, and guide the company's product roadmap including design, enhancements, and development timelines.

Register

The Virtual TriNetX Summit is invitation-only for TriNetX members, customers, and partners. There is no cost to register, however registration is required to attend as well as to receive recordings of presentations.

Please register by clicking here.

UPCOMING WEBINARS

TriNetX Research & Analytics Training Webinar
- September 10, 2020 -
Register here

TriNetX Live New User Training Webinar
- September 10, 2020 -
Register here

HIGHLIGHTED EVENTS

How to Conduct COVID-19 Research with the TriNetX Platform
- Archived Recording from April 7, 2020 -
Click here for more information

Analysis of COVID-19 Outcomes Across Global Real-World Clinical Data
- Archived Recording from April 24, 2020 -
Click here for more information

TriNetX Virtual Summit
- September 22-23, 2020 –
Register here