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Decemeber2020/January 2021 Report

About TriNetX

- Official website: https://trinetx.com
- Founded in 2013
- TriNetX is a global health research networks that connects the world of drug discovery and development by sharing real-world data to make clinical and observational research easier and more efficient
    - They combine real time access to longitudinal clinical data with state-of-the-art analytics to optimize protocol design and feasibility, site selection, patient recruitment, and enable discoveries through the generation of real-world evidence
    - They on-demand platform, datasets, and consulting services connect the life sciences industry to patient data from around the globe
    - It is a market leader in protocol design, feasibility and site selection
- The TriNetX platform is HIPAA and GDPR compliant
- The company was founded on the idea that incorporating real-world data results in better clinical trial design, improves the site selection and patient recruitment process
    - Their goal is to optimize clinical research to bring new therapies to market faster and generate real-world evidence (RWE) to advance the collective understanding of human health

About the Platform

- It is powered by a network of 170 healthcare organization across 30 countries and collaborates with 15 of the top 20 pharmaceutical companies
- Users of the network can access continually refreshed, de-identified data from HER, registries, and claims
- Clients can get answers by using the on-demand platform licensing full datasets, or working with clinical data analysts
- Platform
    - Allows users to build and explore cohorts, compare outcomes, uncover treatment patterns, and more
    - They also connect with healthcare organizations who supply the data
- Datasets
    - Users can download datasets that associate every diagnosis, lab result, and other observation to a date and an anonymized patient ID
    - They can run more precise longitudinal analyses by importing this data into their preferred software package

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- Consulting
    - TriNetX has a Clinical Sciences team represented by analysts, epidemiologists, and evidence strategists with decades of experience in every phase and therapeutic area of research
        - Users can consult with the team
- TriNetX's network of large-scale-up-to-date, longitudinal clinical and claims data is being used by research institutions, individual researchers, and in classrooms
    - The data that TriNetX offers can help with scientific publications, grant submissions, poster presentations
    - The platform also performs advanced analyses which support grant submission, manuscript and poster submissions
    - The network allows like-minded researchers to collaborate
    - Teachers can communicate complex, advanced analyses to students using real data in real time
    - Students can access data for dissertation and manuscript development and explore data to learn more about target populations, compare drug effectiveness, assess real-world drug performance and much more
- Healthcare organizations in the TriNetX network experience the following advantages:
    - TriNetX supplies the hardware for performance
    - TriNetX aligns and maps all the data for collaboration
    - Researchers have access to TriNetX's industry-leading self-service user interface with advanced algorithms and semantic search with hundreds of thousands of synonyms
    - All hardware, implementation, data mapping and training is free
    - Improves a healthcare organization's ability to leverage their own patient data while enhancing its competitiveness and attractiveness for sponsored clinical trial participation
        - Attract more industry-sponsored trials
- Pfizer is using TriNetX for real-time access to clinical, genomic and oncology data to design clinical trial protocols with greater efficiency

Leadership

- The CEO of TriNetx, Gadi Lachman, previously held leadership positions at TriZetto, American Well, and Eliza
    - He was also at Lehman Brothers and was an Officer in Israeli Special Forces
    - Education: MBA from Harvard Business School. LLB in law and B.C. in accounting from Tel-Aviv University
- Ian Read, former CEO and chairman of Pfizer is the Chairman of TriNetX

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Trial Optimization Solutions

- TriNetX helps solve the problem of flawed protocols and costly, avoidable amendments by providing real-time access to patient populations

TriNetX Live

- TriNetX Live enables researchers to analyze patient populations and perform "what-if analyses in real-time
- Each data point in the TriNetX network can be traced to healthcare organizations who are able to identify individual patients
- It allows clinical researchers to:
    - Have self-service access to continuously refreshed clinical data
    - Investigate all attributes and comorbidities of the eligible cohort
    - Determine if a sufficient patient population matches a protocol
    - Analyze inclusion/exclusion criteria and the impact of protocol changes
    - Develop virtual patient cohorts that can be re-identified for potential recruitment into a clinical trial
    - Locate study sites based upon their volume of patients matching a protocol
    - Engage the right contact within the clinical trials office at the right site
    - Predict the number of newly eligible patients at each site in the next 12 months
    - Work with sites that can instantly generate identified patient lists to commence recruitment
    - Gain a path back to the identify of the patient if the healthcare organization decides to participate in their trial

The Network for Oncology Clinical Trials

- The TriNetX network connect clients to clinical and genomic data at healthcare organizations all over the world
    - It seamlessly integrates data from sources including tumour registries, unstructured pathology reports using NLP, molecular genomics, and all leading EMR systems
- This enables them to:
    - Design protocols
    - Locate study sites
    - Assess protocol feasibility
    - Identify eligible patients
- Their algorithm understands treatment patterns to deduce the liens of chemotherapy treatment patients are undergoing
    - In the past, this information was nearly impossible to obtain

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- The algorithm can also determine how many new patients with the specific inclusion/exclusion criteria you seek will become eligible for your trial in the next 12 months on a site by site basis

TriNetX Research

- TriNetX Research combines longitudinal clinical data with powerful analytics, making it the fastest and easiest method for researchers to create real-world evidence
- It enables:
    - Comparative effectiveness to identify treatment that have better outcomes for a given population
    - Generation of value-based evidence to characterize drug efficacy and burden of illness to support payer coverage and patient reimbursements
    - The ability to explore, assess, and download fully anonymized data from a select set of TriNetX Research Healthcare Organizations members and optionally delivered in a format ready to load directly into an OMOP database
    - Having TriNetX do the word directly; delivering custom reports and insights

TriNetX Download

- TriNetX Download makes it easy for clinical researchers to query, license, and download real-word clinical data that is aggregated and harmonized directly from healthcare organizations on a continuous basis
    - Built on the TNX platform, TriNetX Download offers researchers data that is current, HIPAA and GDPR compliant, and clinically broader than traditional licensed research data
    - It also allows for researchers to:
        - Quickly explore available data to assess research feasibility
        - Quickly explore billion of health fact and define new research cohorts through a flexible web-based cohort builder
        - Purchase and access desired research data sets quickly via web download
        - Elevate research ambitions with more extensive clinical data
        - Increase confidence in research findings through improved data diversity and traceability

TriNetX Analyze

- TriNetX Analyze combines and presents deep, rich clinical data with powerful analytics via a single web-based platform
    - It makes it easy for epidemiologists, pharmacovigilance, and clinical researchers to query and analyze real-world data without the cost,

complexity, and lengthy timelines of integrating stand-alone analytics tools and licensing third-party data separately
  - It is built on the TNX platform
  - Provides on-demand access to longitudinal clinical and genomic data and a set of highly intuitive analytic capabilities
  - Enables researchers to explore and compare cohorts
    - Reviewing cohort characteristics prior to an event and comparing outcomes of interest after the event
  - The Query Builder eliminates the need to be an expert in clinical terminology, a data scientist or even familiarity with SQL
    - Researchers can easily find and select the diagnoses, medications, and lab results that define the patients and outcomes they want to analyze
  - The platform allows researchers to explore characteristics across cohorts, side-by-side to assess whether the cohorts are compared/balanced
    - The TriNetX Analyze calculates a "signal" that shows how mathematically significant a difference is across cohorts
  - Researchers can investigate and compare outcomes across cohorts in the following ways:
    - Measures of association
      - Compare incidence of outcomes that occur within the selected analysis time window in terms of risk difference and risk ratio
      - Look at confidence intervals and p-values to assess statistical significance
    - Time-to-event
      - Compare the time for outcomes to occur across cohorts with Kaplan-Meier analysis to determine whether one cohort experiences the outcomes more quickly than the other cohort
    - Lab distributions
      - Compare distributions of lab results to determine whether one cohort achieves different lab results than the other

TriNetX Natural Languages Processing (NLP)

- TriNetX Natural Language Processing Services utilizes sophisticated algorithms to extract clinical facts from physician notes and clinical reports
  - It then links this data with other Electronic Medical Record data and makes the combined data available for assessing study feasibility, protocol design, site selection, and subsequent identification of patients for clinical trials which can be accessed by researchers using the TNX platform
- Data can be derived from clinical documentations such as discharge summaries, progress notes, and pathology reports

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- The TriNetX NLP service is based on technology from Averbis, a text-mining and machine learning company headquartered in Germany
- The TriNetX NLP service runs locally on a TriNetX appliance within the healthcare organization
    - A healthcare organization uploads documents into a target directory, along with the associated metadata and the NLP service processes the comments, extract facts, and associated them with patients and encounters
    - The NLP service then inserts these facts into the organization's TriNetX database, making them available on the TNX platform
- The NLP service does not extract PHI from documents and the process remains separated from the query engine on the appliance, preventing end users from querying documents containing PHI
- Benefits of the TriNetX NLP Service:
    - Embedding NLP to mine clinical documentation can be a significant step toward attracting more clinical trial activity for one's patient population
    - Exposing important clinical data to more accurately define and identify patient cohorts
    - Widening one's population database by exposing unstructured data that had been previously unavailable
    - Enhancing one's value to collaborative networks
    - Increasing available data to enrich one's internal research projects
- If an institutions already has an existing NLP solution they can load the extracted facts using the TriNetX file investigation process to make the data available through the TNX platform

open.trinetx Open Source Library

- The TriNetX library of open-source tools and content, open-trinetx, provides real-world data solutions for technical professionals at pharmaceutical companies and healthcare organizations to analyze and manage their data
- They have partnered with Averbis GmbgH to build a partial mapping from OPS to SNOMED CT
- Their mapping covers top ~2000 most frequently used concepts in OPS and accounts for 90% of procedure data by volume

TriNetX COVID-19 Rapid Response Network

- The newly-created COVID-19 Rapid Response Network is currently represents the largest global COVID-19 dataset
    - This network consists of a subset of data of patients from the larger TriNetX network from healthcare organizations that have confirmed interest in receiving COVID-19 clinical trial and medical chart review opportunities

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    - It includes data about risk factors, comorbidities and outcomes of COVID-19 patients
    - Data is available for analysis through the platform or may be downloaded
- The TriNetX network also allows institutions to quickly connect with hospitals interested in Coronavirus clinical trials

News

January 22, 2021
https://www.prnewswire.com/news-releases/covid-19-research-published-in-the-lancet-rheumatology-finds-rheumatic-disease-patients-are-at-a-reduced-likelihood-of-severe-outcomes-now-vs-early-days-of-pandemic-301212960.html

- Researchers at Massachusetts General Hospital and Harvard Medical School used de-identified real-world data from TriNetX and found that Rheumatic Disease patients are at a reduced likelihood of hospitalization and death now compared to at the beginning of the pandemic
    - This research was published in The Lancet Rheumatology
- They suspect that the finding is multi-factorial- due to increased testing capacity allowing for detection of milder cases, improved supportive care, and improved treatments
- Real-world data enabled them to compare 2 time-dependent cohorts just nine months into the pandemic
- The study had access to de-identified data from nearly 51 million patients across 35 healthcare organizations
- Despite temporal improvement observed, the study noted that there continues to be a considerable risk of morbidity and mortality from COVID-19 among patients with rhematic and musculoskeletal diseases
    - The risk of death remains substantial with 5-6% of patients dying within 3-days of a COVID-19 diagnosis within the study

January 4, 2021
https://www.psychiatryadvisor.com/home/topics/addiction/substance-use-disorder-associated-with-an-increased-risk-of-adverse-covid-19-outcomes/

- In a double-cohort study of 11,124 adults diagnosed with COVID-19 published in Psychiatric Services in Advance, researchers used data from the TriNetX Research Network platform to find that substance use disorder was associated with an increased risk of hospitalization, ventilator use, and mortality
- Reliance on electronic health records data made it impossible to assess potential confounding factors and markers of adverse socioeconomic disadvantages

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January 4, 2021
https://www.docwirenews.com/nephtimes/nephtimes-diseases-and-conditions/diabetes-hypertension/risk-of-adverse-renal-outcomes-in-ckd-patients-with-diabetes-in-discover-ckd/

- During a virtual poster at ASN Kidney Week 2020, Alyshah Abdul Sultan and colleagues reported that they analyzed data from TriNetX and Limited Claims and Electronic Health Record (LCED) discovered that there is an excess risk of adverse renal outcomes in CKD patients with type 2 diabetes compared with those without type 2 diabetes
- This is explained to a large extent by conventional risk markers in LCED but not completely in TriNetX

October 29, 2020
https://www.businesswire.com/news/home/20201029005149/en/Medidata-TriNetX-and-Datavant-Partner-to-Enable-Seamless-Integration-of-Real-World-Data-in-Clinical-Development

- Medidata, TriNetX, and Datavant announced a partnership that will accelerate the use of real-world data to power clinical research
- This partnership will enable users of Medidata's end-to-end clinical research platform to securely link their clinical data with patient consent to des-identified patient data without unblinding the study
- The solution leverages Datavant's Patient Key technology and data ecosystem, as well as RWD from TriNetX's global network of healthcare organizations who participate in this program
- Patients enrolled in a clinical trial utilizing Medidata's solutions will have the option to grant consent for their data to be linkable using Datavant's de-identified Patient Keys to both TriNetX's broad RWD assets and Datavant's open data ecosystem
    - This enables sponsors to cost-effectively study the efficacy and safety of their therapies for many years after the completion of the trial with less risk of losing patients to follow-up
- They suspect that as new vaccines and treatments for COVID-19 come to market faster than every before, the use of real-world data to gather additional safety and efficacy data will be critical to ensuring patient safety and continued evidence gathering
- Medidata, TriNetX and Datavant are pursuing an open, partnership-first approach and look forward to continued collaboration across the industry to modernize the clinical trial infrastructure for patient benefit

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September 21, 2020
https://www.prnewswire.com/news-releases/carlyle-makes-strategic-growth-investment-in-trinetx-acquires-majority-stake-in-leading-global-health-research-network-301134411.html

- The Carlyle Group made a strategic growth investment and acquired a majority stake in TriNetX
- Terms of the transaction were not disclosed
- This investment is a continuation of Carlyle's long-term global commitment to healthcare, in which it has invested more than $15 billion of equity since inception
- Equity capital for the investment came from Carlyle Partners VII, an $18.5 billion fund that makes majority and strategic minority investment primarily in the U.S. in targeted industries