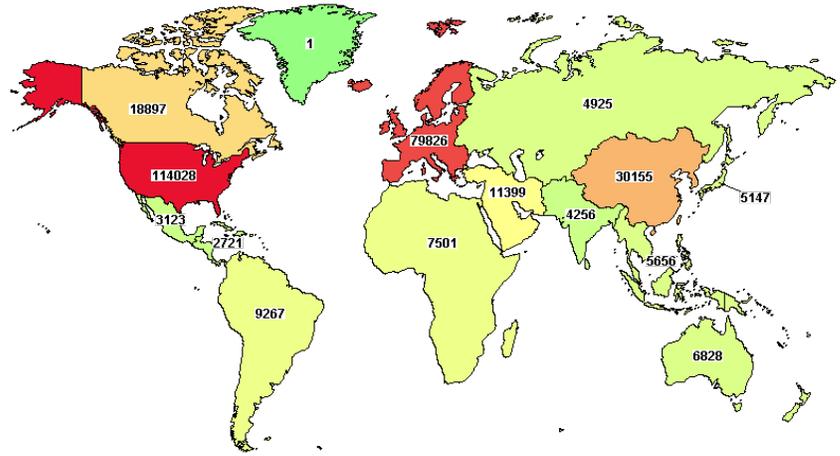


CLINICAL TRIAL SUPPLY CHAIN

SEPTEMBER 2018 TECH BRIEF FOR
THE LIFE SCIENCES TALENT
NETWORK



Numbers on this heat map indicate the number of studies in that location.
Source: <https://ClinicalTrials.gov>

Virtual Clinical Trials Create Jobs

Unlike site-based clinical trials, which require the patient to visit a designated research facility on a regular basis, **virtual clinical trials** are based out of each patient's home. The convenience of a virtual methodology alone increases the number of patients who are able to enroll. For example, those with mobility issues such as the elderly, or patients who live in rural areas can now participate in trials. **Patient enrollment is often the longest stage of a clinical trial** with many trials failing to meet initial targets.

Virtual trials still require the study site to house support staff and to invest in data collection and analysis platforms just as site-based trials. Even so, virtual trials are proving to be **more cost effective**. For example, virtual trials reduce the number of patients who drop out of studies. This is significant since there is no recourse if a patient drops out, their data is lost to the research.

Geographic distribution of a remote trial design allows **more participants** to have an active role in the study. **Omni-channel communication** can include physicians, FDA/NIH, investors and patient advocacy groups.

Jobs created include those in specialty pharmacy and/or logistics, specializing in investigational and specialty drugs including project managers, programmers and administrators. **Third party logistics companies** have entered this niche business area. Virtual trials also create the need for more clinical trial professionals.

Labor Force Takeaway

We can assume that training from a regulatory body will be valued by industry. So, focusing on clinical trial professionals, TAN recommends that in addition to the high-bar credentials now on **the IVC list**, these lower-bar training (no prerequisite) options be added:

FDA's Clinical Investigator Training Course – this 3-day, in-person class is tuition free. Albeit, the location of this training is at a center outside of Washington DC, so it will require overnight stays.

Clinical Research Investigators – a web-based training course from NIH with an online final exam requiring 75% of questions answered correctly to pass. This course is free and **a certificate may be downloaded**.

Reducing Risk in the Drug Development Process

Virtual trials help [reduce risk in the drug development process](#). Take for example a trial making use of remote monitoring devices wherein the data is uploaded to the clinical trial's database. Now investigators can access data in real time, allowing for efficiencies in data cleaning. Rather than an iterative process of testing, a more agile set of decisions are possible. Decisions to terminate a drug's development could also be made faster and with a wider team. This improves patient safety and [reduces expenditure on trials headed for failure](#).

Earlier this year, a [consortium of clinical researchers](#) in New Jersey and Pennsylvania was formed with the express purpose of bringing treatments to market faster. Founding members of Partners in Innovation, Education and Research, or [PIER Consortium™](#) include:

- Atlantic Health System
- Geisinger Health, including AtlantiCare in Atlantic County
- Thomas Jefferson University, including branches in South Jersey
- Drexel University
- Einstein Healthcare Network
- Main Line Health

Drug-development process: illustrated timelines¹

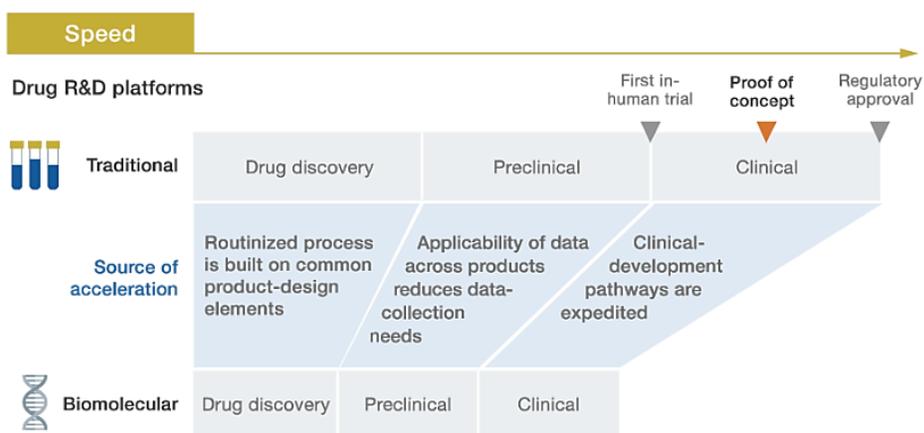


FIGURE 1: [HTTPS://WWW.MCKINSEY.COM/BUSINESS-FUNCTIONS/DIGITAL-MCKINSEY/OUR-INSIGHTS/SHAKING-UP-THE-VALUE-CHAIN](https://www.mckinsey.com/business-functions/digital-mckinsey/our-insights/shaking-up-the-value-chain)

PIER could be a helpful partner for career pathway development and mapping the State's clinical trial ecosystem.

[Clinical trial logistics involves shipment of products](#) to be used in trials to study sites which may be dispersed around the globe, as well as shipment of medical samples to centralized analytical laboratories. New Jersey sites with active practices focused on investigational and/or specialty drug logistics and distribution include:

- World Courier Inc. [Edison](#) – Although not headquartered here, [World Courier](#) has a large operation out of NJ
- [Asembia](#), Florham Park - focuses on the specialty pharmacy segment and offers comprehensive hub services, pharmacy network management, group purchasing services, innovative technology platforms and more.
- [Marken](#), a global company focused solely on life sciences logistics is now a UPS company. UPS has a large NJ operation. Marken lists its differentiators are quality, transport options, end-to-end visibility, global project management and direct to/from patient. It has operations in NY, but it is involved with BioNJ.
- [BioRidge LLC](#), Florham Park is a local company focusing on the targeted distribution of select drugs and pharmacies dispensing specialty pharmaceutical. They provide solutions focused on complex disease states and unique products.

