

# The Medicines Company Improves Investigator Qualification Training

## The Medicines Company (Now Novartis) Applies CTTI's Investigator Qualification Recommendations

### SUMMARY

The Medicines Company (which was acquired by Novartis in January 2020) was involved in a collaborative trial with academic institutions. There, it learned several CTTI-recommended tactics to improve investigator training that has subsequently improved its processes and outcomes.

### GOAL(S)

The Medicines Company had a tactic for keeping its investigators research-ready: build tight-knit relationships, train them to The Medicines Company's needs, and use them repeatedly. As a small company, streamlining to the smallest number of sites possible made sense. However, when The Medicines Company joined a collaborative trial with academic institutions, its leadership learned some additional valuable tools for optimizing investigator training: just-in-time training and role-specific training. It then used CTTI's investigator qualification recommendations to build adoption of these tactics across its own organization.

### CHALLENGES

In a small organization, mistakes are costly, and upending the investigator training system The Medicines Company had long relied on would be risky if not implemented wisely. The organization had to communicate the value of the new tactics it wanted to implement while also maintaining the long-term, personalized relationships on which it has long relied with investigators.

### SOLUTION(S)

CTTI's Investigator Qualification Recommendations, which urge organizations to go beyond repetitive one-size-fits-all training to include individual experience and protocol-specific preparation, offered validation for The Medicines Company's goal. With unbiased perception, the recommendations inspired the team to think outside their traditional box and bring in new ideas.

### TAKING ACTION

The Medicines Company implemented two new concepts into its investigator training. The first was just-in-time training, which focuses on delivering investigators with knowledge and skills when they are needed, rather than providing all required training at one time, prior to starting the trial. This aligns with CTTI's recommendations, which endorse educational programming that is timed to coincide with the conduct of trial activities requiring the knowledge and skills learned. Proponents of just-in-time investigator training report more confident, engaged learners and enhanced performance. The second concept The Medicines Company implemented was role-specific training. CTTI urges sponsors to create role- and protocol-specific education goals that communicate what is new, unique, and difficult about the study to assess and manage risk. Recognition that different members of the site team may benefit from different types of education and experience can accelerate learning and improve investigator performance.

### IMPACT

The Medicines Company successfully implemented both just-in-time training and role-specific training to support its investigators in the conduct of its research.

### ADVICE

Ultimately, good investigator training improves quality, and The Medicines Company felt that adjusting the mode of its delivery in this regard was beneficial. In general, the organization sees promise in challenging the status quo and looking for new and different ways to improve. It recommends CTTI's guidance as a good starting point for such efforts.

### ORGANIZATION

The Medicines Company  
Novartis

### CONTACT

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### ORGANIZATION TYPE

Industry

### IMPLEMENTATION DATE

2018

### TOPIC

Investigators & Sites

### RELATED CTTI PROJECT

Investigator Qualification

**CTTI RESOURCES**

CTTI Recommendations: Identifying Qualified Investigators and Their Delegates to Conduct Sponsored Clinical Trials