

# T. Symons Cites CTTI, Further Harmonizing Quality by Design Principles Globally

## T. Symons Associates Applies CTTI's Quality by Design and Recruitment Planning Recommendations

### SUMMARY

The National Institute for Health and Care Research (NIHR) brought on T. Symons Associates to keep its [Clinical Trials Toolkit](#) updated with current legal and practical requirements for conducting clinical trials. T. Symons found CTTI's Quality by Design and Recruitment Planning recommendations and resources valuable and integrated these into the Clinical Trials Toolkit, which is used internationally by trialists as a go-to resource for best practice. The Clinical Trials Toolkit provides practical advice to researchers in designing and conducting publicly funded clinical trials in the UK and across the world. Using an interactive routemap, the toolkit provides information on best practice and outlines the key requirements for the conduct of clinical trials.

### GOAL(S)

The Clinical Trials Toolkit was initially developed in 2004 to help clinical trialists and R&D managers understand the regulations and requirements for conducting trials in the UK and beyond. The toolkit is based on the London Tube Map, taking users through the clinical trials journey "station by station" with useful advice and guidance at each stop. In 2012, T. Symons Associates was brought on to redesign and manage the Toolkit's content and to continually revise its content to ensure the guidance it provides remains relevant and reflects best practices for clinical trials globally.

### CHALLENGES

Given the Clinical Trials Toolkit's high visibility within the clinical trials community, T. Symons Associates needed to carefully parse available resources to ensure the recommendations included in the updates were relevant, useful, and clearly communicated. T. Symons also considered the potential longevity of any inclusion to the Toolkit. Guidance can become obsolete quickly as the regulatory environment changes. As an international resource used by the UK, US, Japan, and others, it was important to consider the needs and circumstances of all environments and offer solutions that can be applied globally.

### SOLUTION(S)

T. Symons Associates came across CTTI's [Quality by Design recommendations](#) and felt the Principles Document was an ideal resource for the Clinical Trials Toolkit. As a learning tool, it aligned perfectly with the Toolkit's goal of helping those coming into the clinical trial world better understand the right questions to be asked to determine what factors are critical to quality. Avoiding errors, collecting data that is fit-for-purpose, and reducing patient burden are just a few of the many benefits of applying Quality by Design. The approach focuses resources on the errors that matter to decision-making during a trial, such as primary endpoints and patient safety. CTTI also endorses strategic participant recruitment at the initial outset of trial planning as an important consideration. Like Quality by Design, CTTI's [Recruitment recommendations](#) emphasize thoughtful planning early on to optimize recruitment, as well as a focus on evidence-based trial feasibility, site selection, and communication strategies. T. Symons Associates found these recommendations appropriate for the Toolkit as well.

### TAKING ACTION

The Clinical Trials Toolkit has two levels of information: 1) landing pages which signpost readers to best practice requirements for trials, and 2) workstream documents that provide detailed guidance in specific topics. In addition to weaving CTTI's Quality by Design work into the landing page for Trial Management and Monitoring Station, T. Symons Associates also included specific recommendations in the [Monitoring Procedures Workstream Document](#), particularly relating to trial management. In addition, as failure to achieve planned recruitment targets is an enduring issue for trialists, T. Symons also incorporated CTTI's Recruitment Planning work into the Toolkit's [Feasibility and Investigator Selection](#) Station. Incidentally, T. Symons Associates included the most recent CTTI updates to the Toolkit just as the COVID-19 pandemic was taking hold and disrupting the clinical trials community globally. In this environment, approaches to simplify and streamline the clinical trials process while maximizing quality were more essential than ever. From T. Symons' perspective, the application of Quality by Design and strategic recruitment was already on track to become 'the new normal' in clinical research, and COVID-19 only accelerated the speed of adoption. This, T. Symons feels, is one good outcome from the otherwise devastating pandemic.

### IMPACT

The Clinical Trials Toolkit continues to thrive as a resource for the clinical trials community. After the addition of CTTI's Quality by Design and recruitment planning work, there was an uptick in website hits, suggesting the community found the recommendations valuable. At the most recent assessment, the Clinical Trials Toolkit was getting thousands of hits per month.

### ADVICE

T. Symons Associates stresses the importance of continued collaboration across the clinical trials community. Trialists tend to be very generous with information sharing, so there is never a need to reinvent the wheel. Rather, T. Symons would love to see increased collaboration across entities like CTTI and other thought leaders in the clinical trials space. As we move toward a learning health system that will benefit the entire international community, creating forums and connections to share best practices will be vital.

### ORGANIZATION

T Symons Associates Pty Ltd

### CONTACT

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### ORGANIZATION TYPE

Professional Service

**IMPLEMENTATION DATE**

2020

**TOPIC**

Quality, Recruitment

**RELATED CTTI PROJECT**

[Quality by Design Recruitment](#)

**CTTI RESOURCES**

[CTTI Recommendations: Quality by Design](#)

[CTTI Recommendations: Efficient and Effective Clinical Trial Recruitment Planning](#)