

CAPTURING AND LEVERAGING CLINICAL TRIAL DESIGN INSIGHTS

A HIGHPOINT SOLUTIONS WHITEPAPER

Pharmaceutical companies and medical device manufacturers run clinical trials all the time. So why are so many clinical trials designed and built as though there were no precedents? It's as though neither the insights nor the experiences gained from previous trials could be brought forward to serve as the foundation upon which to construct new clinical trials.

And in a way that's precisely the problem: It's not that organizations learn nothing worth re-using from previous clinical trials. Rather, it's that most organizations have inadequate tools for capturing and acting upon that knowledge. There are meeting minutes in Word documents, spreadsheets with budget information and data points, PowerPoint presentations to showcase progress and milestones. But all these elements are related by...what? Few companies have any framework upon which to connect these objects or understand the relationships they imply. Various documents may showcase decisions and results, but they may not show clearly how decisions were made. They may not enable you to understand what fruitless paths your teams might have travelled before accomplishing a task.

Without access to those insights, you risk having to explore those same fruitless paths in the future. You risk wasting time, money, and resources recreating processes and procedures that you have already created. And not just once. Without tools that enable you to capture the knowledge, relationships, and the insights related to achieving those results, you risk wasting this same time and recreating these same processes and procedures with every clinical trial you undertake.

Design Memory

To break this cycle, pharmaceutical companies and medical device developers need what we might call a design memory tool. One aspect of such a tool would enable an organization to capture and organize all the development and management events associated with the development of a clinical trial. A second aspect of such a tool would enable you to build upon the structures and insights that arise from your experiences in previous trials.

Consider what studies have shown about the state of clinical trials today:

- **On average**, 33% of the issues raised by regulators stem from a finding that a program's design has not generated sufficient evidence to support a claim.¹
- **On average**, some 22% of the data collected during a clinical trial does not support any of the trial's objectives.²

Summary

- Organizations conducting clinical trials often lack a mechanism for capturing and leveraging data relating to the design and management of the clinical trials themselves.
- In the absence of re-usable insights, organizations often waste time and resources planning and executing clinical trials as though conducting one for the first time.
- A flexible design memory tool, designed with the needs of clinical trials in mind, can enable an organization to design and manage a trial more effectively—and enable that organization to leverage insights and best practices efficiently when building out the next clinical trial.



¹ Witch E. Tracing the roots of quality. 5th DIA European Workshop on Medical/Technical Writing, Paris. 2003.

² Getz KA, Stergiopoulos S, Marlborough M, Whitehill J, Curran M, Kaitin KI. Quantifying the Magnitude and Cost of Collecting Extraneous Protocol Data. Am J Ther. 2015 Mar-Apr; 22(2); 1124. See www.ncbi.nlm.nih.gov/pubmed/23429165.

A design memory tool can enable you to defy these averages. It can help you capture the data you will need and not waste time and resources capturing data you will not need. It enables you to build on your experience to anticipate regulators' questions and requests, thus designing trials that can ensure that you capture the evidence that regulators will want.

In short, a design memory tool enables you to gain actionable insights that you can then reuse in subsequent trials. You gain an ability to create a set of unique, tailored templates upon which to construct future trials, templates that enable you to build upon the knowledge and best practices that evolve within your organization over time. To put it another way, a design memory tool enables you to avoid recreating the wheel each time you need to move forward. Instead, you can move forward using the wheels you have already built, tested, and tuned to meet the needs of your organization.

Managing the Art of Clinical Trial Design

There are those who will argue that clinical trials cannot map to a rigid template—and we would agree. Every trial is unique. Yet some needs persist from trial to trial in a given class of pharmaceutical products and medical devices. Trial developers require the ability to:

- Work with teams in different locations and time zones
- Capture, track, and manage both structured and unstructured content
- Manage workflows and metadata
- Monitor and report on progress
- Exchange information securely with other enterprise tools and assets (including executive dashboards, portals, data repositories, web services, communications and content management systems, and more)

Moreover, they need tools and services to facilitate:

- Decision making (including review, commentary, voting, etc.)
- Decision tracking and auditing
- Content traceability and historical reference analysis
- Event and milestone tracking (with tools for alerts, alarms, and notifications)

Given all the variables reflected in these needs, it becomes clear that a design memory tool must focus on facilitating the art of clinical trial design. It must help an organization accommodate the critical dynamics of each trial as it evolves, and provide enough flexibility for those aspects of each trial that may be unique. At the same time, it must be able to help the organization build upon and reuse those aspects of a given trial that can enable a new trial to get underway faster, at lower cost, with fewer errors and wasted efforts.

"HighPoint's Design Memory Tool allows us to leverage our existing usage of Salesforce.com to provide a solution to a persistent problem. The tool was easily adopted by both operations as well as IT as the Salesforce.com platform is intuitive and easy to use and the necessary support structures were already in place. The simplicity of the effort has us thinking about other uses of the Salesforce.com platform."

– AstraZeneca

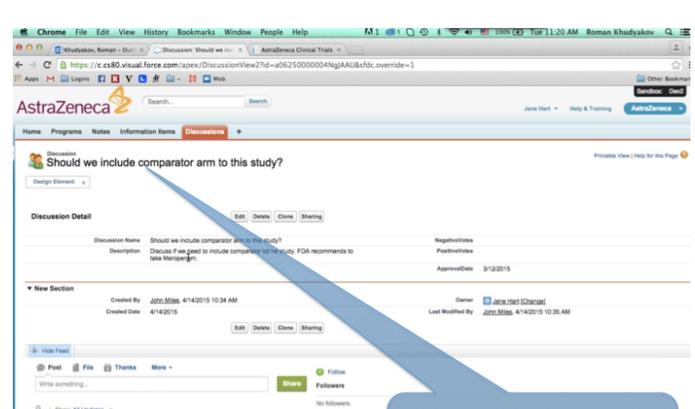
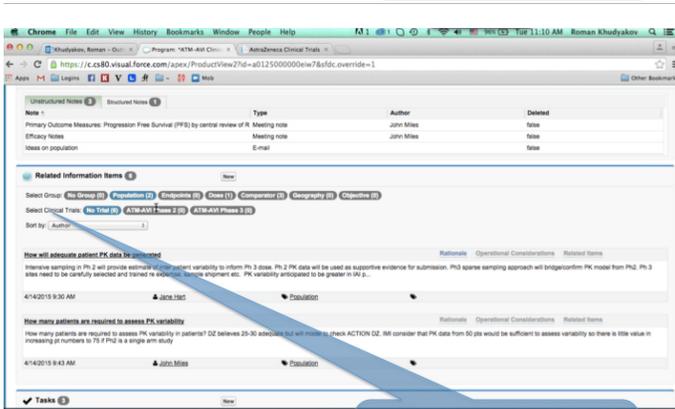
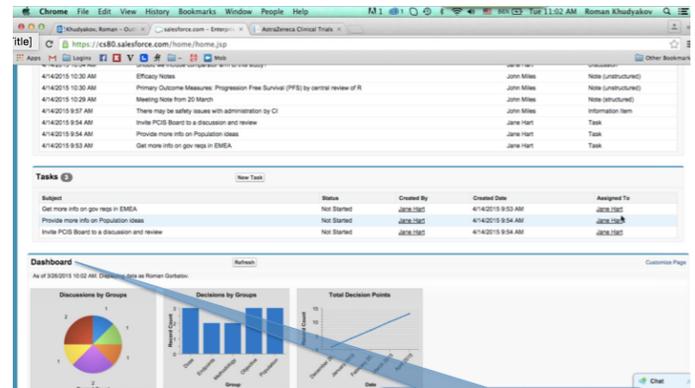
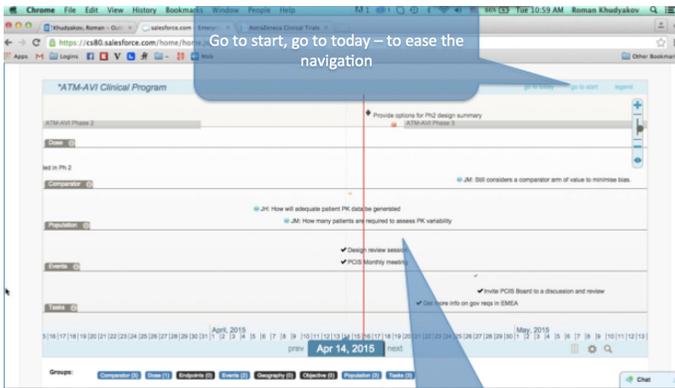


Delivering a Design Memory Tool

HighPoint offers a design memory tool expressly designed to meet the needs of organizations conducting clinical trials. Based in the cloud and leveraging the same core object management technology that drives salesforce.com, the HighPoint design memory tool enables an organization to capture any kind of structured or unstructured data relating to the development, management, and execution of a clinical trial. It provides mechanisms for connecting events, decisions, and data so that an organization can always gain insight into who made which decisions, how they arrived at that decision, and why they made the decision they did. It provides mechanisms for tagging events and documents, for searching for information, even managing workflows relating to decisions and events pertinent to the clinical trial. And, it provides all these features with the security, flexibility, and resiliency that an enterprise operating in the world of clinical care requires.

Furthermore, the HighPoint design memory tool provides mechanisms to roll out new clinical trials based on the experiences and the insights captured in previous trials. The best practices that emerge from past experience are not lost; they become the framework upon which new trials can be set in motion. Indeed, it is not always clear—during the life of a clinical trial—which decisions and which actions will prove to be of greatest significance. Clarity comes with reflection, and—because the flexibility of the underlying object management system enables you to capture everything—the design memory tool that HighPoint has developed enables you to build upon those elements that, in retrospect, are discovered to be of greatest importance.

HighPoint Solutions offers a design memory tool expressly designed to meet the needs of organizations conducting clinical trials. This tool enables an organization to capture any kind of structured or unstructured data relating to the development, management and execution of a clinical trial.

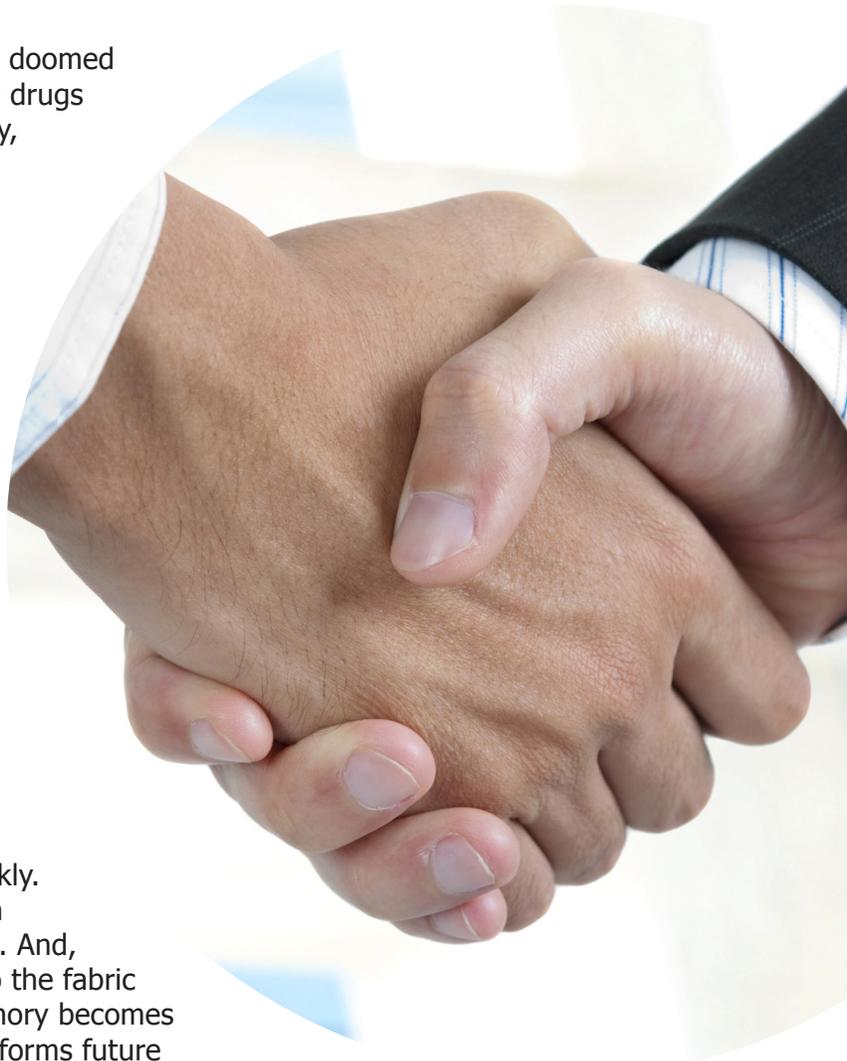


Summary

It has been said that those who do not know history are doomed to repeat it. Given the real-world pressures to bring new drugs and devices to market quickly, safely, and cost-effectively, organizations need to find ways to build on the past in a constructive manner.

The HighPoint Solutions design memory tool ensures that you'll make the most of your experience and insights when it comes to the creation and management of clinical trials.

A design memory solution from HighPoint Solutions ensures that you can make the most of your experience and insights when it comes to the creation and management of clinical trials. You can capture designs and decisions, data and best practices. You can build on what works to construct and commence trials more quickly. You can build on your experience to ensure that you can answer proactively the questions that regulators will ask. And, you can integrate all this knowledge and experience into the fabric of your organization, thus ensuring that this design memory becomes a core part of an enterprise memory that lives on and informs future efforts, even as the individuals who have contributed these insights move into other roles or leave the organization.



To learn more about how HighPoint Solutions can help you improve your ability to design and manage clinical trials, please contact Lior Keet or Jim Goldfinger, or visit www.HighPointSolutions.com.

Lior Keet - HighPoint Solutions

VP of Life Sciences R&D
lior.keet@highpointsolutions.com

Jim Goldfinger - HighPoint Solutions

VP of Client Value Networks & Strategic Partnerships
james.goldfinger@highpointsolutions.com

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US: 301 E. Germantown Pike • East Norriton, PA 19401 • +1 800.238.1230
EU: Cours de Rive 13, CH-1204 • Geneva, Switzerland • +41 0.22.735.95.81
www.highpointsolutions.com