Clinical Data Aggregation Working Group

Purpose

The Clinical Data Aggregation Working Group ("Working Group") is aimed at guiding pharmaceutical, biotechnology, and clinical research partners through the process of defining, developing and deploying information management tools that unlock the value of clinical data. Automating the data aggregation, transformation and validation tasks associated with analytical data preparation for clinical trials can trim significant time and costs from the clinical trials process.

The Working Group will address key data management challenges that include: incompatible systems between collaborating organizations, highly manual data transformation processes, and the lack of data standardization and its impact on cost, quality and efficiency. As part of our efforts, we will work to provide the biopharma industry with enhanced capabilities in the following key areas: (a) aggregating data from multiple sources; (b) mapping disparate data to a uniform, consistent data structure; (c) cleansing and validating data to ensure a reliable basis of analysis; and (d) delivering accurate predictive and prescriptive analysis.

The proposed solution is a set of standards compliant tools that enable biopharma's to deploy reusable processes for automating the transformation of clinical data (current and legacy). The initial output of the group will be rapidly-deployable clinical data management tools that deliver higher quality clinical information, faster and at less cost.

Core participants include: TBD – Active recruitment open through December 20, 2013.

Innovation Accelerator (working group type). Accelerating innovation through collaborative, multi-organization, public-private, interdisciplinary, and issue-focused working groups. They combine proven approaches for facilitating innovation, along with methodologies and tools that can be applied to solve key business challenges.

Contact Information. Ron Garnett | email: rkgarnett@ironSAGE.com | phone: 202.643.4766.

Goals

To unlock the significant scientific and business value hidden in clinical assets; and to improve the quality and cost-effectiveness of clinical research. To improve efficiency, quality and speed in collecting, managing, analyzing, reporting and assessing clinical data.

Objectives

To enable pharmaceutical, biotechnology and CROs to deliver clinical data services faster, better and at less cost.

To leverage existing clinical data and derive additional value.

To preserve knowledge from, and extend the use of, prior studies in a reusable fashion.

To enable clinical investigators to analyze events and trends across a series of trials.

To decrease startup and reporting time for clinical trials.

To reduce the rate of human error in data management processes.

To drive the adoption of enhanced data standards and automated clinical data integration.

Why You Should Join Us. By some estimates, as much as 65 percent of the time it takes to conduct a clinical trial is spent on data interchange among collaborating entities. The process entails a series of exchanges between sponsors and investigators, between sponsors and CROs, between CROs and labs, between sponsors and regulators, and so on. The growing volume and complexity of these data interactions is seen as a primary cause for escalating costs in clinical research and drug development.

The Clinical Data Aggregation Working Group will identify innovative solutions to successfully improve the efficiency, quality and speed in collecting, managing, analyzing, reporting and assessing clinical data. Ultimately participants will gain the tools necessary to streamline data management tasks, reduce cost and increase the value derived from clinical data.

Working Group Commitment. The invitation-only working group will consist of 5-10 core participants, each bringing a particular area of subject matter expertise, understanding and influence. Additional innovation partners may be sourced and vetted as needed. The majority of the group activity is expected to be conducted over 4 months, beginning with the Working Group Summit. The following are the estimated levels-of-effort for participants:

- *Meetings* - coordinated every 4-6 weeks ~ 90 minutes
- *Conference calls* - coordinated once per month or as needed
- *On-line collaboration* - ongoing updates of working documents, communications, and resources
- *Reports* - monthly progress reports and agendas for upcoming meetings

Meetings dates, times, and location are coordinated around the schedules of the group. In-person participation is preferred, however call-in lines will also be provided.

Activity Roadmap. The following is the basic activity outline for the group by stage:

1. Challenge Overview - setting preliminary group focus
2. Stakeholder Onboarding - signing-on initial participants
3. Group Charter - finalizing participants, goals and objectives
4. Group Virtual Summit - inaugural group meeting
5. Feasibility Evaluation - determining solution requirements
6. Innovation Partners - sourcing and vetting innovation SMEs
7. Group Accelerators - preparing use-cases and prototypes
8. Integration Teams - pilot implementations and reviews
9. Collective Working Group - go-to-market and commercialization strategies
10. Next Steps - growth funding and full-scale development

The working group is currently in Stage 2.

Next Steps. To participate with this working group, kindly respond to Ron Garnett at (rkgarnett@ironSAGE.com) as soon as possible with: (1) whether or not your organization will be represented; and (2) the contact information (phone and email) for that person.

We have established a web site for the project (http://ironsage.com/course/clinical-data-aggregation-working-group-014/) and have put some informative materials on the web concerning the group. Additional information will be available via secure login. The first meeting is expected to convene in mid-January. The actual date and time will be coordinated to meet the availability and convenience of the participants. A DC meeting location will be announced; however, a video/teleconferencing facility will also be made available.

Ron Garnett will be coordinating this working group. If you require additional information or have any immediate questions, please contact Ron at (rkgarnett@ironSAGE.com or 202.643.4766). We look forward to working with you and your organization.

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