

A grayscale background image showing a group of people in a professional setting, possibly a meeting or collaborative work environment. They are looking at documents and talking to each other.

KNOWLEDGE BASE: CIRCLES

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INTRODUCTION

The concept of a “study” seems deceptively simple — a research protocol, one or more investigators and data subjects. In practice however many challenges arise – legal/regulatory compliance, funding, patient enrollment, patient compliance, pre-mature termination, IT infrastructure, clinical coordination, statistical and clinical significance, multi-center administration, article preparation, publication, and time constraints to name a few.

A Circle not only makes the execution and publication of that study far more efficient than traditional approaches; it unlocks its full value. It does so for small private studies, as well as complex multi-center trials.

CIRCLE ELEMENTS

A study becomes a Circle through the integration of “Circle Elements” into its design and execution. Different elements support various aspects of a Study, but each of them enhances efficiency and value creation. Importantly, Circle Elements are implemented through a single platform, and most can be added at any time. This provides a turnkey experience for all Study participants, as well as maximum flexibility.

Examples of Circle Elements include:

- The ability easily to add any number of Investigators within or across institutional or national boundaries.
- The addition (or later exclusion) of Team Members to assist the Investigator(s).
- Implementation of protocols, consents, patient education materials, patient outcomes measures and other assets in multiple languages.
- A suite of Roles and Permissions specifying access to Personal Data, aggregated datasets, creation of Reports, and other matters.
- The ability to add variations to research protocols which allow individual Investigators to accommodate the specificities of their practices, while retaining the “canonicity” of data collected against the master research protocols.
- Powerful, flexible and intuitive Report generation capabilities.
- A desktop and mobile patient portal (Benchmarc™) with excellent user-experience for patients and their investigator-clinicians.
- Flexibility in the presentation, execution and maintenance of Consent Forms.
- The ability to choose server locations for the storage of Personal Data.
- Conversion of aggregated data sets into FHIR HL7, CDISC or other messaging formats.
- The ability to create customized Scoring Groups.
- Development of posts, or longer articles, together with video and other multi-media presentations for Publication.

THE VALUE OF CIRCLES

Circles result in four major types of value:

Cost Reduction

Circles reduce the costs associated with

- Patient recruitment, enrollment and follow-up.
- Data and document auditing and verification.
- Sub-Investigator recruitment, collaboration.
- Multi-center administration.
- IRB/IEC submissions.
- Legal/regulatory compliance.
- Patient attrition.
- Patient education materials.
- Premature termination.
- Investigator fees.
- Development of statistical and clinical significance.
- Translation into various messaging formats (FHIR HL7, etc.)
- Publication.

Reduction of Actual and Contingent Liability

- Paper to digital data transfers.
- HIPAA/GDPR and similar personal data protection.
- Inadequate securing and maintenance of patient consents.
- Documentation of adverse events.

Monetization of Results

- Investigator fees, including funding for Investigator-Initiated Studies.
- Honoraria for conference presentations, other influencer activities.

- Supplemental procedures, new standards of care, service lines.
- Support for reimbursement.
- Product discounts.
- Product incubation, license fees.
- Training and education seminars.

Professional/Business Advancement

- Publication of results through traditional channels (articles, conference presentations, etc.) and social media.
- Development of “influencer” status.
- Ongoing collaboration with peers and experts around the world.
- Education, training, clinical efficiencies.
- Superior patient engagement.

RELATED ARTICLES

Study

Investigator Initiated Trials

Sub-Investigator recruitment, collaboration

Benchmarc™

Publication

Reports