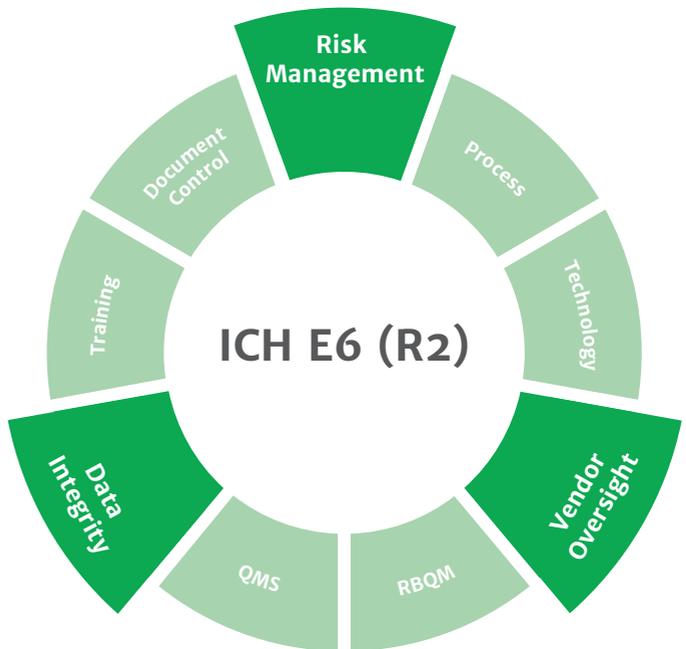


ICH E6 (R2)

CHAUCER DELIVER ON THE OPPORTUNITY OF ICH E6 (R2)

We have taken the core elements of R2 and delivered something for our clients that takes their implementation of R2 **from compliance to opportunity**. We support all areas of change for R2 but core elements we highlight are: **Risk - Vendor Oversight - Data Integrity**. We deliver on the opportunity to drive **higher quality across** clinical trials and operations.



Since the adoption of ICH E6 (R2) by the EMA and FDA, we have learned a lot from the implementations in small and large Life Science organizations – not one size fits all. Everyone needs a tailored solution based on their complexity and attitude to risk.

Our aim is to manage risk in a positive way through your organizations culture; manage interaction with vendors in a way that makes sense for everyone, and manage your data integrity through good data stewardship.

RISK MANAGEMENT

Our interpretation ICH E6 (R2) section 5.0 is based on our 30 years of experience in managing risk in the energy industry, and for the largest infrastructure project in Europe. With our cross industry experience, our key learning in risk is that; you must change the culture to sustain the change.

Our teaching in how to define a risk and manage a risk is the game changer. The Change Management activities require top level stakeholder management, training and communication that instill a positive way of looking at risk. Using

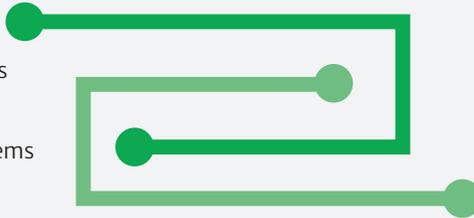
risk to drive higher quality in your clinical trials and vendor oversight. Our practice looks at risk management as a positive driver to focus you on quality by design. Managing risk in this way means you do not get any nasty surprises within your trial program, across your vendors and from the outside.

“Risks should be considered at both the system level and clinical trial level”

THE ADDENDUM:

SYSTEM LEVEL

- CROs & Vendors
- SOPs
- Computer Systems
- Facilities



- Study Design
- Protocol Development
- Investigators Role

TRIAL LEVEL

We offer the following services:

Change Management



Best Practice



Gap Analysis



Bow Tie Methods



Implementation



Risk Management Toolset



Phased Risk Breakdown Structure



VENDOR OVERSIGHT

Vendor Oversight is inherent across the whole of Good Clinical Practice. The accountability of all tasks undertaken in a trial ultimately stops with the sponsor.

The art of oversight starts with the selection of the vendor, and becomes effective through the initial engagement activities; defined through your contract

and technical definition. Chaucer has experience of these activities and can set you on the road to success, not just through the processes we help you define but also in your organizational structure to make sure you have the right roles and talent to be successful.

We offer the following areas of support and services:

Organization Structure



Vendor Selection



Metrics & Performance



On-Boarding



Inspection Readiness



Aligning Standards



Audit & Compliance



Managing Risk



Documentation



Clinical Trial Conduct



Quality Assurance



Business Processes



DATA INTEGRITY

Life Science data processing has become increasingly complex in recent years with more sophisticated clinical trial designs, complex outsourcing models and the expansion of new technologies for collecting and processing patient data. Chaucer has taken the Data Integrity component of R2 a step further and introduced **Data Stewardship** which crosses the boundaries of the process and technology and introduces the day to day importance of knowing what is happening to your clinical data.

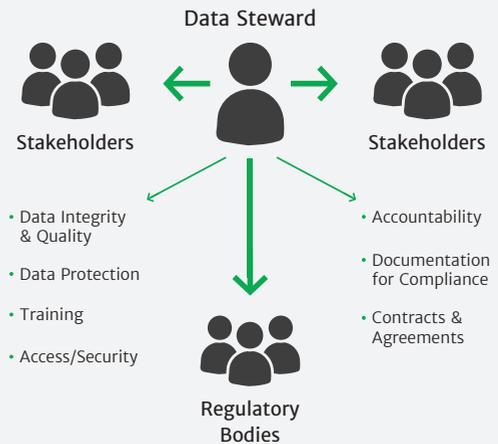
The Data Steward ensures that the quality, consistency, usability, security, and availability of data are maintained through the data lifecycle with the implementation of policies, procedures and rules.

The importance of this capability takes through the identification and management of data risks to quality, trial conduct, and patient protection. This is not just internally but also across your data vendors. Chaucer can support your business in setting up its data stewardship service, minimizing any risks you may have in your data management practices that could result in costly delays or fines to your organization.

Data Stewardship

Data Governance

Strategy, Principles, Policies, Standards



We offer the following services:

- Data Integrity Risk Assessment
- Technology and Organization Solution Recommendations to Mitigate Risks
- Data Governance Framework Build
- Training and Awareness Workshops
- Delivery of Data Stewardship BAU

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