

# Risk Management in Clinical Trials

## Risk Based Approach

### Identifying Risks.....



Critical element	Example risk considerations
Subjective endpoint (e.g. rater scales)	Rater qualifications; training; inter-rater consistency; ensuring correct person performs the assessments etc
Objective endpoint (e.g. lab value)	Conditions for maintaining sample integrity; lab methods and reporting; scheduling to ensure sample is taken etc
Patient Reported Outcomes	Training; provision of technology; assessment of PRO data for AEs; ensuring the PRO is completed etc
IMP	Stability [storage conditions (temperature, lighting, security)]; point of use (clinic, subject's home); Preparation (as is or reconstituted); Administration (topical, intravenous etc); availability (automatic resupply?);
Informed Consent	Multiple ICF versions; consent/assent; ethics approvals; adequacy of process documentation; qualifications of person performing interview etc
Specific data point	ALCOA standards (Attributable, Legible, Contemporaneous, Original, Accurate); integrity of data capture method, validation of calculations etc

# Clinical Trials Risk Management

**Tobias Bleicker**



## **Clinical Trials Risk Management:**

The Top Books of the Year Clinical Trials Risk Management The year 2023 has witnessed a remarkable surge in literary brilliance, with numerous engrossing novels captivating the hearts of readers worldwide. Lets delve into the realm of popular books, exploring the fascinating narratives that have charmed audiences this year. Clinical Trials Risk Management : Colleen Hoover "It Ends with Us" This heartfelt tale of love, loss, and resilience has captivated readers with its raw and emotional exploration of domestic abuse. Hoover masterfully weaves a story of hope and healing, reminding us that even in the darkest of times, the human spirit can succeed. Clinical Trials Risk Management : Taylor Jenkins Reids "The Seven Husbands of Evelyn Hugo" This spellbinding historical fiction novel unravels the life of Evelyn Hugo, a Hollywood icon who defies expectations and societal norms to pursue her dreams. Reids absorbing storytelling and compelling characters transport readers to a bygone era, immersing them in a world of glamour, ambition, and self-discovery. Clinical Trials Risk Management : Delia Owens "Where the Crawdads Sing" This captivating coming-of-age story follows Kya Clark, a young woman who grows up alone in the marshes of North Carolina. Owens crafts a tale of resilience, survival, and the transformative power of nature, captivating readers with its evocative prose and mesmerizing setting. These bestselling novels represent just a fraction of the literary treasures that have emerged in 2023. Whether you seek tales of romance, adventure, or personal growth, the world of literature offers an abundance of engaging stories waiting to be discovered. The novel begins with Richard Papen, a bright but troubled young man, arriving at Hampden College. Richard is immediately drawn to the group of students who call themselves the Classics Club. The club is led by Henry Winter, a brilliant and charismatic young man. Henry is obsessed with Greek mythology and philosophy, and he quickly draws Richard into his world. The other members of the Classics Club are equally as fascinating. Bunny Corcoran is a wealthy and spoiled young man who is always looking for a good time. Charles Tavis is a quiet and reserved young man who is deeply in love with Henry. Camilla Macaulay is a beautiful and intelligent young woman who is drawn to the power and danger of the Classics Club. The students are all deeply in love with Morrow, and they are willing to do anything to please him. Morrow is a complex and mysterious figure, and he seems to be manipulating the students for his own purposes. As the students become more involved with Morrow, they begin to commit increasingly dangerous acts. The Secret History is a brilliant and gripping novel that will keep you guessing until the very end. The novel is a warning tale about the dangers of obsession and the power of evil.

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