Fact Sheet

Risk Assessment & Management

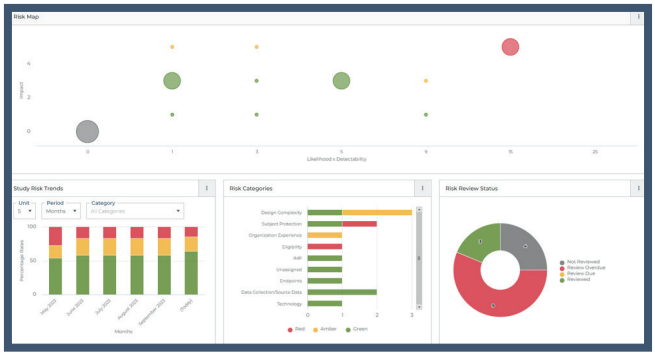
Intelligent risk management tools you'll love because they make your job so much easier.

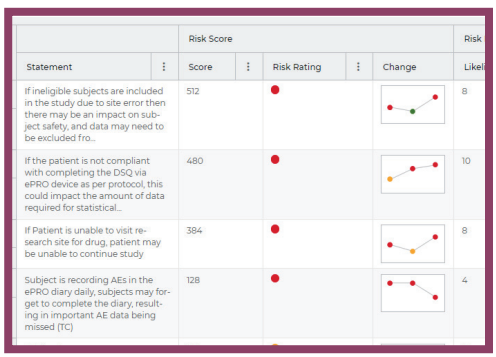
OPRA-RAM: smart software for better risk management

As simple to use as a spreadsheet, but much more powerful. Why? Because it's built around your processes and does all the hard work for you. The outcome? Better data quality, decision making, and efficiency resulting in safer patients and happier users. Always be audit and inspection ready with OPRA RAM.

Benefits

- Up and running in minutes
- Control all your important risks
- Show real-time, up-to-date data
- Share risk information with everyone
- Assign actions and follow-up
- Drive efficiency and target your biggest issues
- Build confidence and collaboration



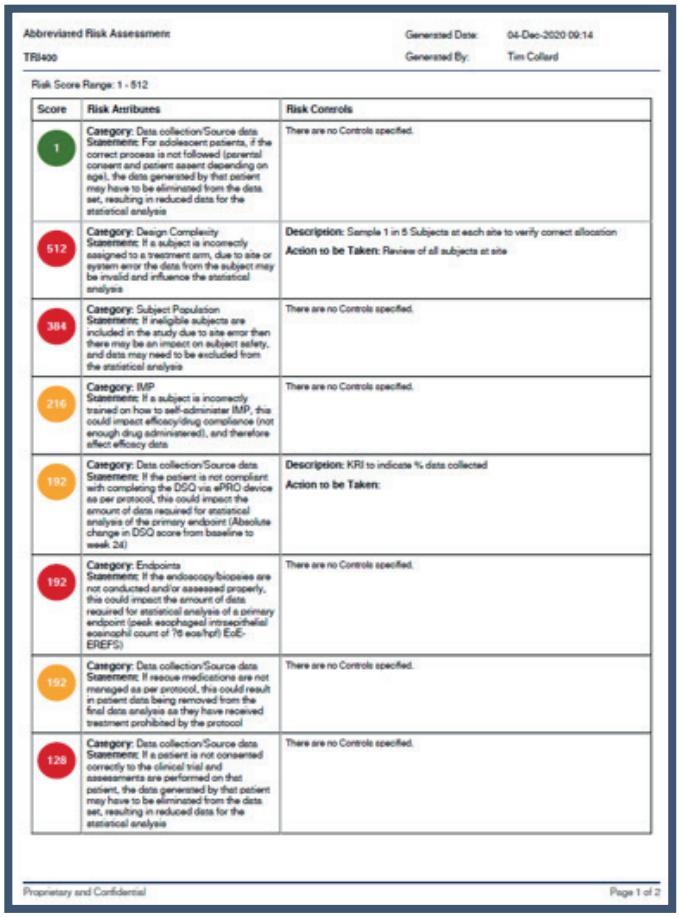


- Accelerate your review process
- Justify your risk decisions and actions
- Link critical factors with risks and controls
- Create study specific risk scoring models
- Display your data, your way
- One-click reporting
- Always audit and inspection ready

Features

Whether you're a Sponsor or CRO; whether you're a Clinical Trial Manager running 10 studies, or a CRA needing to record a new Site risk; whatever your role in clinical trial management, you'll love OPRA RAM because its 'spreadsheet easy', but much better.

- Identify and capture data and processes critical to quality
- Create and import risk and control libraries
- User configurable risk scoring model based on Impact, Likelihood, and Detectability
- Ability to sort and filter risks by score, study, functional owners, controls, etc.
- Document why decisions and actions were taken
- Ongoing risk identification, review, and reporting
- Communicate risk control and ownership
- Easy to add new risks as the study progresses
- Securely share information with internal and external users and stakeholders
- Timestamped reports
- Full audit trail including history of who entered or changed data and when



Abbreviated Risk Assessment

Generated Date: 04-Dec-2020 09:14

TRI400

Generated By: Tim Collard

Risk Score Range: 1 - 512

Score	Risk Attributes	Risk Controls
1	**Category:** Data collection/Source data **Statement:** For adolescent patients, if the correct process is not followed (parental consent and patient assent depending on age), the data generated by that patient may have to be eliminated from the data set, resulting in reduced data for the statistical analysis	There are no Controls specified.
512	**Category:** Design Complexity **Statement:** If a subject is incorrectly assigned to a treatment arm, due to site or system error the data from the subject may be invalid and influence the statistical analysis	**Description:** Sample 1 in 5 Subjects at each site to verify correct allocation **Action to be Taken:** Review of all subjects at site
384	**Category:** Subject Population **Statement:** If ineligible subjects are included in the study due to site error then there may be an impact on subject safety, and data may need to be excluded from the statistical analysis	There are no Controls specified.
216	**Category:** IMP **Statement:** If a subject is incorrectly trained on how to self-administer IMP, this could impact efficacy/drug compliance (not enough drug administered), and therefore affect efficacy data	There are no Controls specified.
192	**Category:** Data collection/Source data **Statement:** If the patient is not compliant with completing the DSQ via ePRO device as per protocol, this could impact the amount of data required for statistical analysis of the primary endpoint (Absolute change in DSQ score from baseline to week 24)	**Description:** KRI to indicate % data collected **Action to be Taken:**
192	**Category:** Endpoints **Statement:** If the endoscopy/biopsies are not conducted and/or assessed properly, this could impact the amount of data required for statistical analysis of a primary endpoint (peak esophageal intraepithelial eosinophil count of 76 eos/hpf) EoE-EREFS)	There are no Controls specified.
192	**Category:** Data collection/Source data **Statement:** If rescue medications are not managed as per protocol, this could result in patient data being removed from the final data analysis as they have received treatment prohibited by the protocol	There are no Controls specified.
128	**Category:** Data collection/Source data **Statement:** If a patient is not consented correctly to the clinical trial and assessments are performed on that patient, the data generated by that patient may have to be eliminated from the data set, resulting in reduced data for the statistical analysis	There are no Controls specified.

Proprietary and Confidential

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