## Innovation & Transformation

# **Transformation to Risk Based Monitoring**

## Are your clinical operations organized to optimize RBM?

#### **Benefits**

- Streamlined data to define site monitoring activities
- Realignment of roles and responsibilities to core needs
- Cost reduction by off-shoring non-core activities
- Potential integration of selected data monitoring activities with CDM activities for improved outcomes
- More effective analytics and relationship driven site management strategy

Transformation, not evolution, through improvements in People | Process | Technology





### Current processes in clinical operations generate high cost but often add little value. Efficiency gains can be made in the following areas:

- R&D operations, including the real time availability of data for informed decision making
- Seamless and coordinated trial operations, including on-time patient recruitment and delivery of drugs to site
- Quality by design, to ensure processes and outcomes are "right first time"
- Compliance with ever changing regulations, including submissions
- High cost of drug development and the need to improve efficiency in all clinical functional areas

#### TAKE Solutions provides an integrated approach leading to impactful results

- Therapeutic area experts provide relevant insights for integration of proactive quality planning steps into your SOPs, governance structure and study operations
- Industry leading technologists with RBM expertise to assess systems architecture and data flow, capabilities, data governance, challenges and quality roadmap
- Resource capacity and capability assessment tools that clarify gaps and options in relation to best practice RBM model

#### **Deliverables**

- Current core vs non-core capabilities and capacity
- Current systems map and data flow schema
- Process and governance gap analysis
- Standardized tools and templates for core activities
- Transformation roadmap with change management plan
- O Case for change for senior management and use in building alignment of stakeholders

#### **About TAKE Solutions**

TAKE Solutions delivers domain-intensive services in Life Sciences. In the fast-growing Life Sciences space, TAKE offers clients a unique combination of full-service Clinical, Regulatory and Safety services backed by unique technology expertise. Our range of services span from clinical trials to regulatory submissions to post-marketing safety, all backed by insights derived through proprietary industry networks forums. With a team of leading Life Sciences experts, best-in-class systems and processes, and bespoke, industry-specific technology and analytics, TAKE delivers successful outcomes for clients. Our global roster of clients includes large and small innovator biopharmaceutical companies as well as generics manufacturers. With operations spread across North America, Europe, Asia, and South America, TAKE is a Public Company, listed in India on the Bombay Stock Exchange and the National Stock Exchange. Led by a team of industry stalwarts and domain experts, TAKE has been growing steadily with FY18 revenues touching INR 15,872 Mn, (USD 246 Mn).

#### For more information

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