## Effective Data Management and Efficient Operations in Clinical R&D

## indegene®

# We help you expedite completion of clinical trials with efficient data management

With our technology-led innovation and domain expertise we manage diverse clinical data to optimize trial experiences, and expedite study start-up and completion,. Our comprehensive clinical data management offering encompasses refining data requirements, eCRF design, process building, integration, and amendments to study build that are essential to accelerate study execution and improve the quality of study results.

## Clinical operations organizations face unique challenges

- ~16 weeks required to create the database from the past clinical trials data
- Inability to reuse and repurpose the database
- Inefficient and expensive manual processes taking 1,000+ hours for data transfer, review and standardization

## Here's why Indegene Clinical Data Management

- Faster database build with integration of advanced technologies
- Expertise in building Global Library for large and emerging pharmaceutical companies across Therapeutic Areas
- Transformation of clinical trials data to meet the CDISC SDTM standards

## Here's how we can help you

Bold Vision build capabilities, culture Accelerate and scale up outcomes Personalize experience

Future Ready<sup>¶</sup> Healthcare

Healthcare expertise, content and conversations

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Fit-for-purpose technology **indegene**<sup>®</sup>

Agile operations and culture

## Here's what Indegene Clinical Data Management includes

End-to-End Clinical Data Management Support

#### Study Set-Up

- CRF Design and
  Development
- EDC Configuration
- Data Management Plan
- Data Validation
  Specification
- Database Build & UAT
- Data integration Set-Up

#### **Study Conduct**

- Data Management and Validation
- Clinical Data Review and Query Management
- Manual Listings Specification and Programming
- Clinical Data Coding
- SAE Reconciliation
- Vendor Data Handling & Reconciliation
- Site and User Management

#### **Study Closeout**

- Interim and Final Database Lock
- CRF PDF Generation
- Blind Data Review Meeting
- Data Archival & Documentation

We extend services across therapeutic areas, ensuring foolproof data collection. We do this:

- With our global experienced team who use multiple technologies and comprehensive data sources that offer near real time visibility
- By collaborating through digital platforms, our network of partners, overseen by clinical and medical advisors, leading to successful study outcomes

## Our capabilities

#### 250+

Experienced resources

15+

areas

Therapeutic

#### 100+

New study builds

#### 10+

Years of experience in CDM

#### 1000+

Study migrations

## Some of the key outcomes we have delivered

**↓**25-50%

Time for eCRF design and deployment **30-40%** 

Time and cost for discrepancy management

### **30-40%**

Time for database cleaning and review

### ↓ 30-40%

Time for closeout documentation and data transfer Timeline compliance

99.2%

Quality

99.8%

### **About Indegene**

We are a technology-led healthcare solutions provider. We combine deep industry expertise with fit-for-purpose technology in an agile and scalable operating model. Many of the leading, global healthcare organizations rely on us to deliver effective and efficient clinical, medical, and commercial outcomes every day. From strategy to execution, we enable healthcare organizations be future ready.



## **i**ndegene®