

EDC | DM | IWRS | CTMS | ePRO

Data Analytics, eClinical Solutions & Managed Services

Standard Trials | Virtual Trials | Remote Trials | Home Healthcare Supported Trials



**Data Driven Studies:
Faster and smarter
results delivered.**

Unified eClinical Suite

Smarter, easier studies

Better Decisions

Focused on small to

Medium Life Sciences

axiom
real-time metrics™

| solutions@axiom.cc | www.axiommetrics.com |

COVID-19

Research is managed globally by Fusion.

Axiom's Activity
During
COVID-19



EDC | DM | IWRS | CTMS | ePRO

key modules in use in COVID-19 Studies

Standard Trials | Virtual Trials | Remote Trials | Home Healthcare Supported Trials



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Data Driven Studies

Real-Time Reporting

Lower Operational Costs

Axiom is conducting global clinical studies for Oxford University, Emergent Biosciences and many others.

**Axiom is responding to the unique and unprecedented
circumstances of the COVID-19 global pandemic.**

Being a global company, we are responding to our clients in this time of change and need for collaboration and innovation. Axiom is delivering solutions to our clients at an accelerated pace. Trials are going live in weeks. Key

COVID needs include various ePRO Module configurations, multiple languages, home health care data collection and mobile device support. Critical data analysis in real-time are enabling managers of these studies to quickly navigate the study planning and decisions.

Global clients

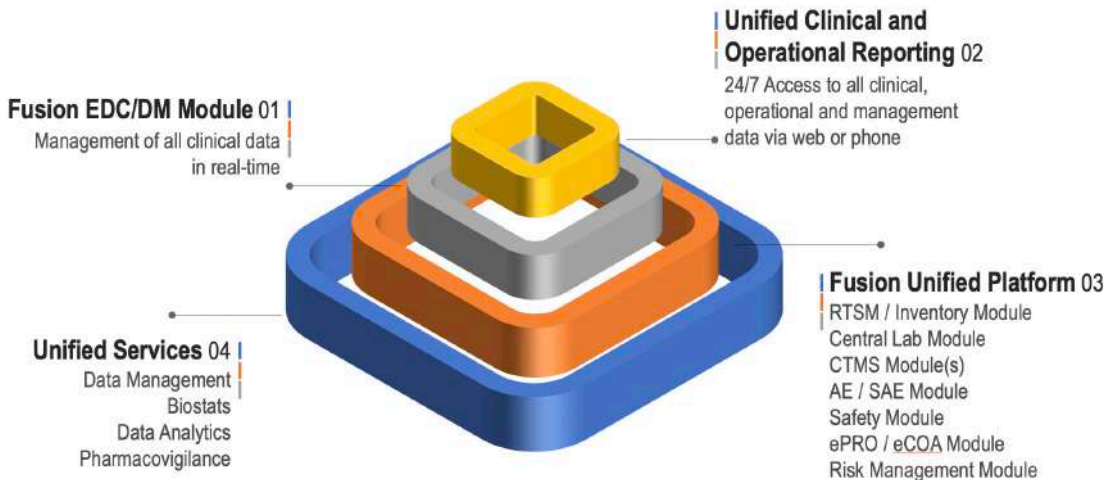
Chat with us to see how we can solve your
eClinical and Study Operations needs.



axiom
real-time metrics™

Truly Unified.

Data Driven Studies enhance critical results.



EDC | DM | IWRS | CTMS | ePRO

Data Driven Studies

Real-Time Reporting

Lower Operational Costs

Making complex study, clinical operations, Data Analytics, DM/PV management tasks easier to manage.

That's what a well designed and executed eClinical platform delivers. That is what Axiom's Fusion eClinical Suite delivers in hundreds of studies globally. Real-time study reports in 2 clicks. Integrated randomization Centralized device/drug supply management. Issue payments directly from Fusion. Manage AEs & SAEs, Safety & MedWatch and much more.

Stop using spreadsheets to manage your clinical studies.

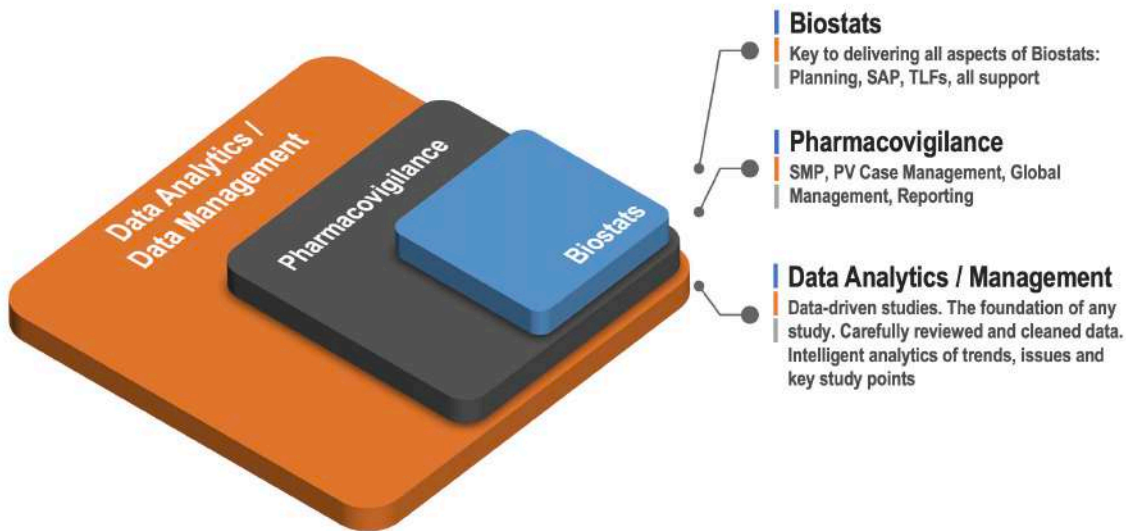
Global clients

Chat with us to see how we can solve your
eClinical and Study Operations needs.



DM, Biostats, PV & Study Operations Simplified.

EDC + DM + IWRS + CTMS + Reporting + Safety





Focus on your study design, not the change order.

Unlimited, no-fee changes during your database configuration so that you can focus exclusively on the design of your study.

Focused on small to medium Biotech, Device and CROs.

19+ years - 750+ studies

**10,000
active
sites.**

**Oncology / CNS /
Dermatology /
Cardiovascular**

**US+
Europe+
Canada+
Asia**

**150+
device
studies**

**40+
countries**

**Randomize here.
IWRS+ Device & Drug
Inventory Management**

**Fixed-Cost Model.
No hidden charges or
fees. Clear budgets.**

**65+
CE/PMA
studies**

**EDC+DM+IWRS+IVR+AE/SAE Tracking+ Safety+Central Lab+
Imaging+Inventory Tracking+Payment Tracking+Reporting**

15 **Fusion** eClinical Suite

EDC | DM | IWRS | CTMS | ePRO

Data Driven Studies

Real-Time Reporting

Lower Operational Costs

OPTION

01

**Selected
Modules**

OPTION

02

**EDC +
Selected
Modules**

OPTION

03

**Complete
Fusion
Suite**

Basics/Data Analytics

EDC/DM

eSource

Pre-Screening Log

Data Coding

General Log

Risk Management

ePRO/eCOA

ePRO/eDiary App

ePRO/eDiary Web

ePRO/eDiary Phone

eConsent

Safety

AE/SAE Tracking

Safety Management

IWRS/RTSM

IWRS/IVRS

CTM Tracking

Data Import / Adjudication

Central/Local Lab Import

Adjudication

Imaging

Data Import

SAS On-Demand

CTMS

CTMS Dashboards

Deviations Management

Study Start-Up

Payment Tracking

Trip Reporting

eTMF

**Single
Log-On.**

Know More. Real-Time Reporting.

Fusion Reporting Tools deliver:

- **Subject Activity Management**
- **Key Performance Indicators**
- **ePRO Compliance Reports**
- **Data Progress Reports**
- **Site Management**
- **Operational Activity**
- **Risk Profile Tools**
- **Data Review Tracking**
- **Clinical Review Tracking**
- **Patient Profile Reports**
- **Clinical Review Reports**



EDC | DM | IWRS | CTMS | ePRO

Data Driven Studies

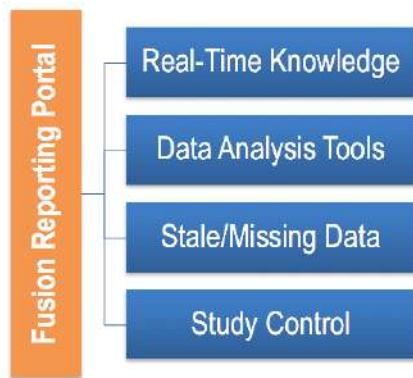
Real-Time Reporting

Lower Operational Costs

75+ Real-Time Reports.

Live access to PM, randomization, modules,
clinical data reports,
DSMB reporting and data listings.

Getting access to the status of your study shouldn't require a PhD in computer science. Real-time study reports in 2 clicks. Pull reports in seconds. Export them to



“Access your
entire **real-time**
study details &
clinical data
in 2 clicks.”



Randomization IWRS/RTSM

Fusion RTSM Tools

Simple to complex randomization, fully integrated and linked to inventory.

- Central vs. Site-specific Randomization
- Stratification and Cohort Management
- Cap enrollment at Study, Site & Strata-levels
- Eligibility requirements tailored to fit your protocol and ensure sufficient inventory
- Visualize enrollment progress with dashboards and configurable reports



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Data Driven Studies

Real-Time Reporting

Lower Operational Costs

Inventory Tracking

Global Inventory Awareness

Including inventory levels, requests, shipments and pending activities

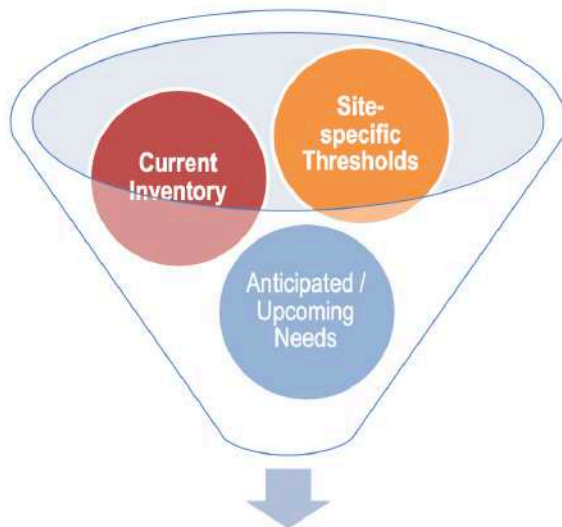


AI-Driven Auto-Resupply

Specifics

Requests are raised for supplies based on a multitude of factors including:

- **Current Inventory:** Fusion accurately captures the sites current inventory including inventory in transit / pending site receipt, upcoming expiries and accountability
- **Site-Specific Thresholds:** Set resupply levels for buffer inventory / safety stock based on actual enrollment activity and expectations
- **Anticipated / Upcoming Needs:** Based on historical and scheduled activity



Fusion RTSM AI Review
[Analyzed ongoing/daily]



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Data Driven Studies

Real-Time Reporting

Lower Operational Costs

Ease of Managing/Adding Studies

Specifics

Global Reporting, Single Sign-On

Global Inventory Management

Study
1

Study
2

Study
3

Study
4

Study
5+

EDC



DM



IWRS/
IVR



Safety



Reporting



CTMS

Randomization

Specifics

IWRS + ePRO + Compliance Standalone or Unified IWRS

Handle all aspects of your randomization/IWRS/IRT/RTMS via Axiom Fusion.

Standalone IWRS solution or delivered within Axiom Fusion as a total suite.



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Data Driven Studies

Real-Time Reporting

Lower Operational Costs

Inventory Tracking

Specifics

Axiom Fusion's Inventory capabilities means tasks and key information are totally centralized & automated.



ePRO Module

Android and iPhone applications.

Real-time data streamed directly into your study.

Link randomization and compliance directly into Fusion so you know what's happening with your patients.

Powerful, integrated ePRO tools.

Globally deployed.



ACME 502

Axiom Fusion Treatment - ePRO Compliance Log

Date: 29/Mar/2017

Time of Report: 5:08 PM EST

Country	Site	Subject Number	Number of Days in Study	Date of Last Diary Entry	Number of Diary Entries on Last Diary Day	Diary Entries Overdue	Percentage of Compliance
United States	010 - Westbrook Hospital	010-8002	80	20/Apr/2015	2	No	75.1%
United States	010 - Westbrook Hospital	010-8007	76	20/May/2015	1	No	85.9%
United States	010 - Westbrook Hospital	010-8008	45	27/May/2015	9	No	79.3%
United States	010 - Westbrook Hospital	010-8009	31	08/Jun/2015	15	No	86.8%
United States	010 - Westbrook Hospital	010-8012	21	15/Jun/2015	13	No	89.4%
United States	010 - Westbrook Hospital	010-8015	10	06/Jul/2015	7	No	84.1%
United States	010 - Westbrook Hospital	010-8017	3	17/Jul/2015	4	No	98.5%
United States	010 - Westbrook Hospital	010-8018	1	20/Jul/2015	2	No	89.9%
United States	012 - Duncan Memorial	012-8003	76	14/Apr/2015	8	No	92.9%
United States	012 - Duncan Memorial	012-8004	53	11/May/2015	10	No	88.5%
United States	012 - Duncan Memorial	012-8009	43	28/May/2015	11	No	74.2%
United States	012 - Duncan Memorial	012-8007	41	02/Jun/2015	7	No	84.7%
United States	012 - Duncan Memorial	012-8008	21	11/Jun/2015	7	No	96.4%
United States	012 - Duncan Memorial	012-8010	13	15/Jun/2015	8	Yes	73.0%
United States	012 - Duncan Memorial	012-8011	10	29/Jun/2015	14	No	82.2%
United States	012 - Duncan Memorial	012-8012	7	09/Jul/2015	12	No	79.7%

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Data Driven Studies

Real-Time Reporting

Lower Operational Costs

Fusion ePRO Tools

Capture your ePRO results using Axiom's web, IVR or mobile device tools. Review real-time results and ensure subject compliance.

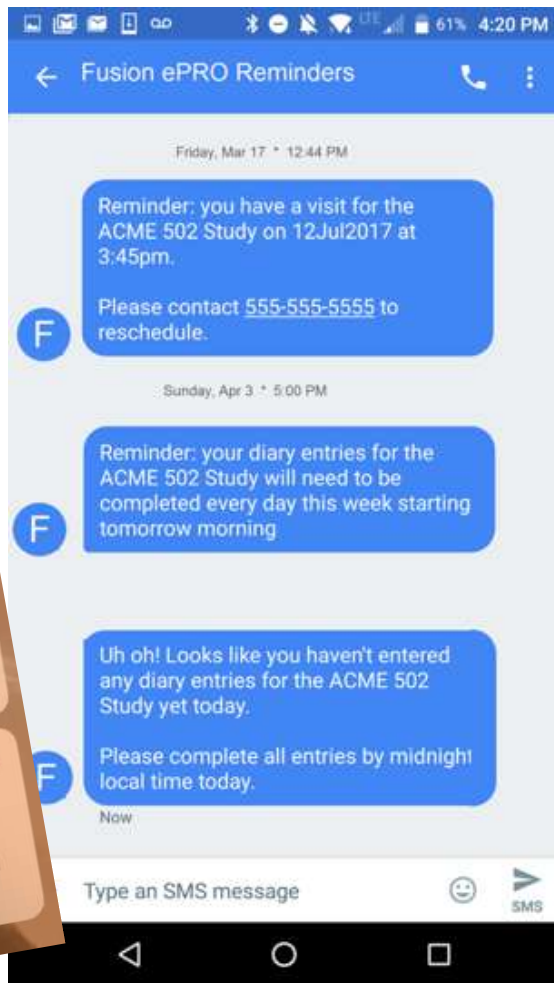


- **Choose the tools to manage your ePRO / eDiary needs**
 - Mobile Application via iPhone or Android
 - Web Portal Access
 - Telephone Entries (IVR)
- **Provide Key Reminders for Compliance**
 - Push Notifications from the Application
 - Text reminders
 - Email reminders
- **24/7 Real-Time Reporting Access**
 - Complete reporting of all ePRO data
 - ePRO Compliance Reports



ePRO Notifications

Smart, dynamic, local time-zone controlled notifications.



**Axiom's global teams can provide
Total Device Management.
Configuration, Shipping, Data Plans,
Device Support. Effortlessly delivered.**



Axiom Total Device Management

Axiom provided and managed Devices

App: Android or iPhone
Web: Tablet or iPad

Data Plan Management

Complete Device Shipping and Accountability in real-time

Device Delivery

BYOD

Download Fusion Mobile directly to Patient Devices

Support all languages and countries

Coordinator can instantly download Patient Set-up instructions

Axiom can provide Complete Patient Kits



EDC

+

DM

+

IWRS/
IVR

+

Safety

+

Reporting

+

CTMS

axiom
real-time metrics™

Manage Safety Events in Fusion. AEs + SAEs + Safety Tracking & Reporting.



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Data Driven Studies

Real-Time Reporting

Lower Operational Costs

One Login. Centralized.

SAEs + PV + EDC + DM

No need for a separate safety database.

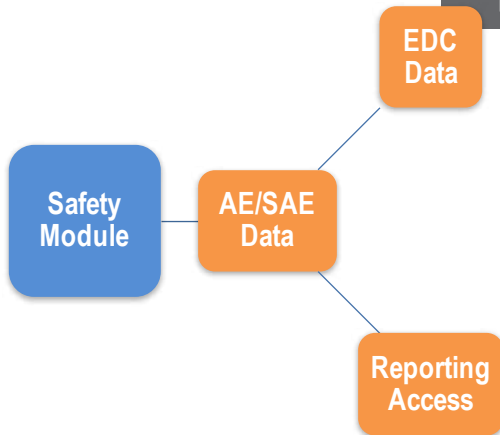
How about managing your AE/SAEs/SADEs and overall safety reporting from within Fusion? Track events. Create narratives.

Communicate with site personnel. Generate regulatory forms, such as MedWatch and others. Track reportability. No reconciliation. No manual data tracking. Smart notifications for key data.

Total safety management. All within Fusion eClinical Suite.



Pharmacovigilance Solutions & Services.



Unified PV Solutions & Services delivered

Axiom's global PV solutions and 24/7 team enable complete management of PV events directly within Fusion.

Use Axiom's PV Module to manage your next study's safety requirements. 24/7 reporting. Tracking all overdue events.

Enable Axiom's PV team to deliver the complete solution - technology and services to manage the total safety events.



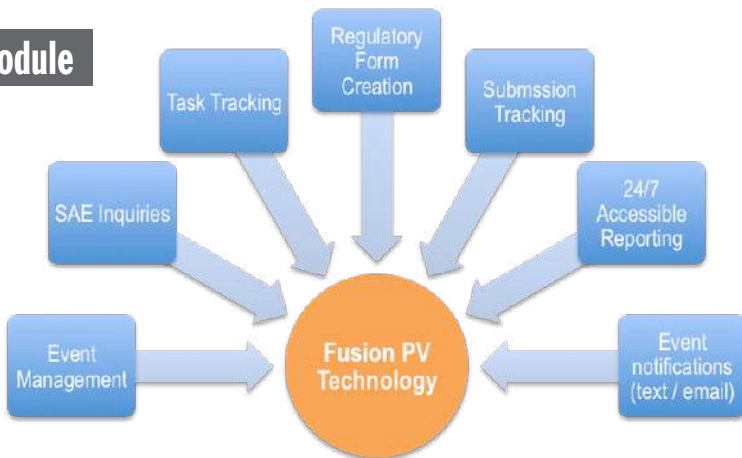
EDC | DM | IWRS | CTMS | ePRO

Data Driven Studies

Real-Time Reporting

Lower Operational Costs

Fusion PV Module



PV Services

Strategic Consulting



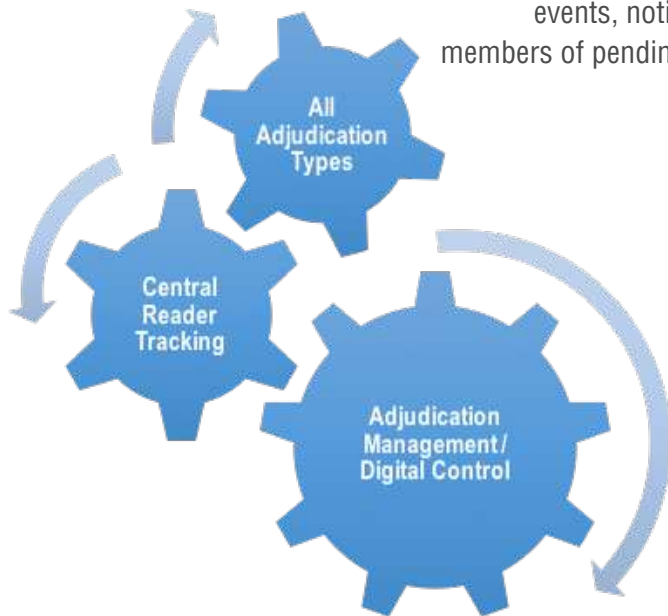
Operational Consulting



Adjudication Module

Centrally manage all forms of adjudication tracking, data, results

Delivers electronic package to adjudicator, manages all adjudication events, notifies team members of pending events.



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Data Driven Studies

Real-Time Reporting

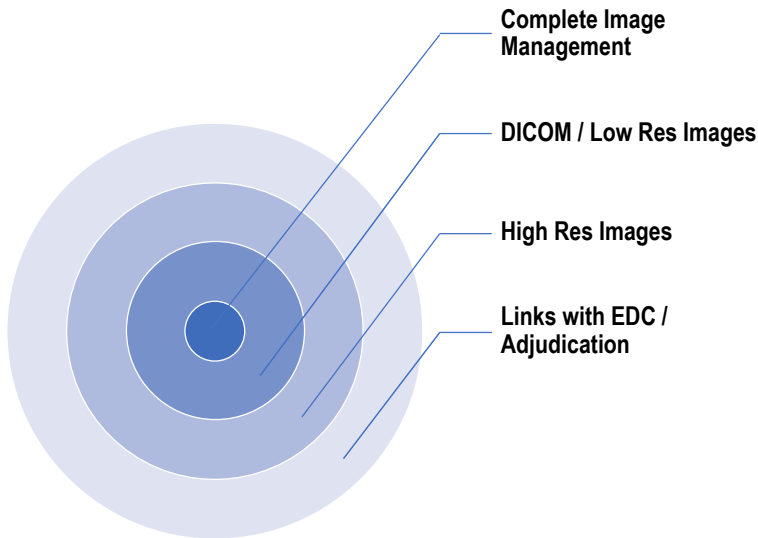
Lower Operational Costs

Imaging Module

Manage all images within Fusion.

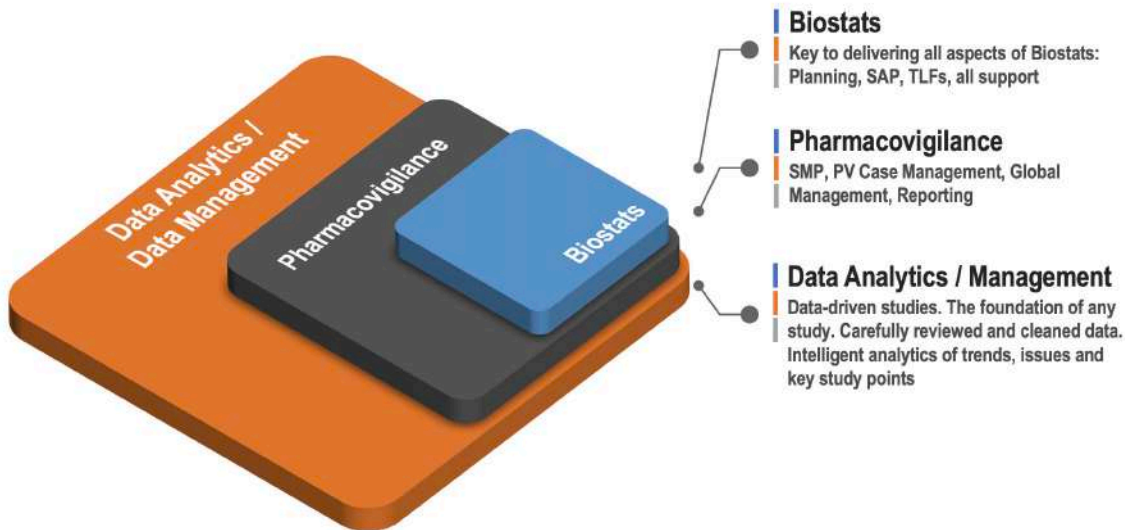
Enable central reading.

Integrate your image requirements.
Control your image management centrally.
Links with key Fusion Modules.



DM, Biostats, PV & Study Operations Simplified.

EDC + DM + IWRS + CTMS + Reporting + Safety



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Data Driven Studies

Real-Time Reporting

Lower Operational Costs

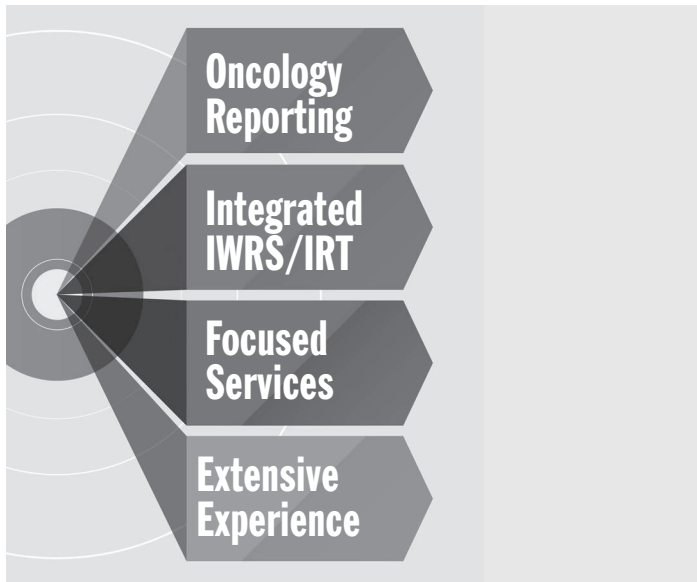
Axiom is an Embedded Partner.

Clinical Science	Clinical Consulting	Protocol Development	Outcomes Planning	Medical Monitoring	Results Analysis	
Data Management	Overall Planning	Data Review / Trending	Medical Coding	Clean Subject Tracking	Site / Monitor Visit Support	
BioStats	Planning / Randomization	SAP Development	BioStats Programming [CDISC]	PK/PD Analysis	Statistical Reporting	
Pharmacovigilance	Strategic Planning	Operational Consulting	Safety Plan Consulting	Event Management	Regulatory Reporting	DSMB Management
Operations	Strategic Planning	Study Planning	Site Management	Contracting/ Payment Management	Monitoring	Hub Management





Oncology Studies *via* Axiom Fusion



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Data Driven Studies

Real-Time Reporting

Lower Operational Costs

Axiom delivers **Oncology Solutions.**

Reporting Tools

Patient Profile
Reports

Tumor Response Calculations /
Response Tracking

Assessment
Reports

Lab Listings

AE/SAE
Listings

Enrollment Forecasting / KPIs

Biomarker
Reports

Unified Modules

CTM Tracking

Randomization

IRT / Predictive Re-Supply
[Manage drug efficiently]

Central Lab
Import

AE/SAE
Module

Safety Module

CTMS Module

Module Reports

IP Lifecycle
Report

Case Narrative
Listings

SAE
Management

Enrollment
Tracking

Data
Dashboards

Services

Data
Management

Pharmacovigilance

Clinical
Science

Project
Management

Medical
Monitoring

Key Data Points

Patient Profile
Reports

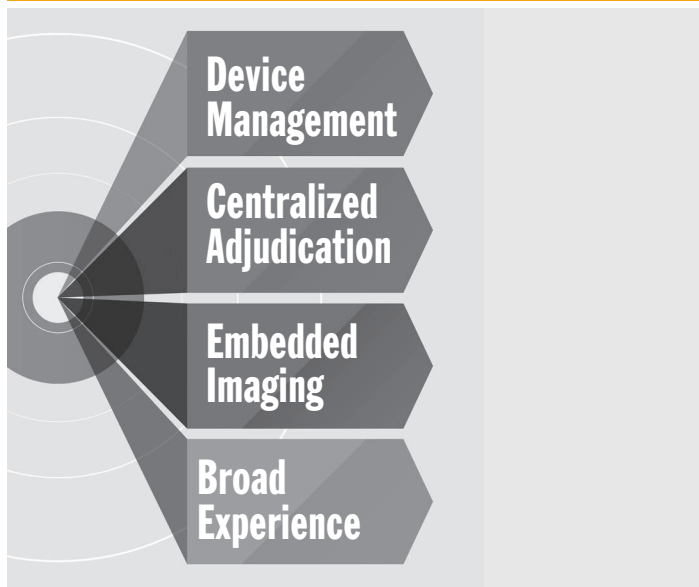
Biomarker
Tracking

Response
Assessments





Device Studies *via* Axiom Fusion



EDC | DM | IWRS | CTMS | ePRO

Data Driven Studies

Real-Time Reporting

Lower Operational Costs

Axiom delivers
Medical Device
 research solutions.

Reporting Tools	Patient Profile Reports	Adjudication Management	Image Oversight	Lab Listings
	AE/SAE/SADE Listings	Enrollment Forecasting / KPIs		
Unified Modules	CTM Tracking	Adjudication	IRT / Predictive Re-Supply [Manage inventory efficiently]	Image Import
	AE/SAE/SADE Module	Safety Module	CTMS Module	ePRO (Device/Web) Randomization
Module Reports	Hand-Carry Tracking	Case Narrative Listings	SAE/SADE Management	Enrollment Tracking Data Dashboards
Services	Data Management	Pharmacovigilance	Clinical Science	Project Management Medical Monitoring
Key Aspects	Hand Carry Management	Adjudication Oversight	Adjudicator Resourcing Tools	



Results-oriented partners are hard to find.

Axiom functions as an extension of the overall clinical study team, focused on the study success, partnered through the challenges and the successes.

Clinical data and operations is at the heart of the project. Choose an innovative eClinical technology partner that embodies every aspect of the thinking and execution you expect for your studies.



Reach us:  solutions@axiom.cc | 877.321.9191 | www.axiommetrics.com |



EDC | DM | IWRS | CTMS | ePRO

Data Driven Studies

Real-Time Reporting

Lower Operational Costs

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