



Time for the Next Step: Graduate to a Compliant EDC Solution with DFnet

19 March 2025

Questions

Use the Chat feature in Teams at any time to ask questions or share feedback.

Recording

You'll receive a link to the webinar recording via email after the event.

Resources

Check out previous webinars and more about DFnet at <https://dfnetresearch.com>

Speakers



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United States



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United States



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Better Data. Better Insight. Better Care

About DFnet

- Providing clinical data management solutions & services that help researchers move science forward
- 30+ years of evolution in clinical data management
- Our CDMS and suite of professional services help optimize your clinical studies: faster setup, higher quality data, and the flexibility to run your trials exactly the way you want
- Cornerstone for data management across research sectors, phases, therapeutic areas, and sample sizes

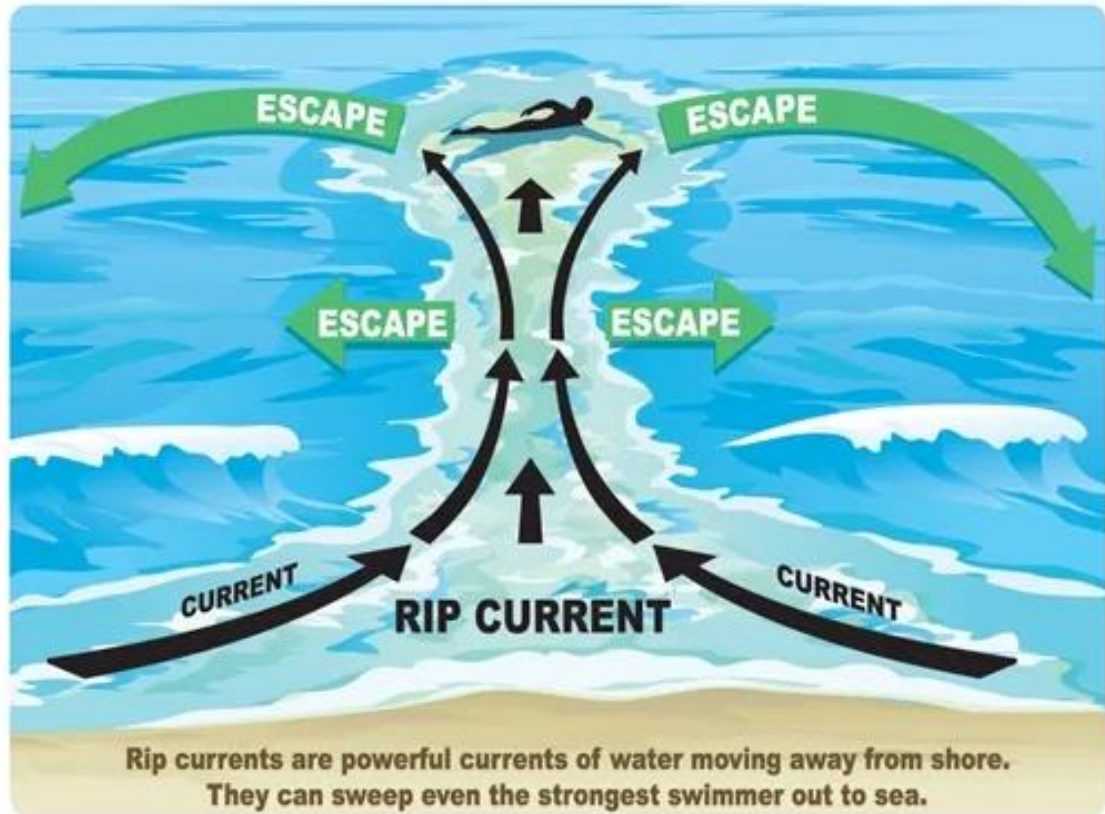


South Africa | USA | Canada

Why Does Compliance Matter?

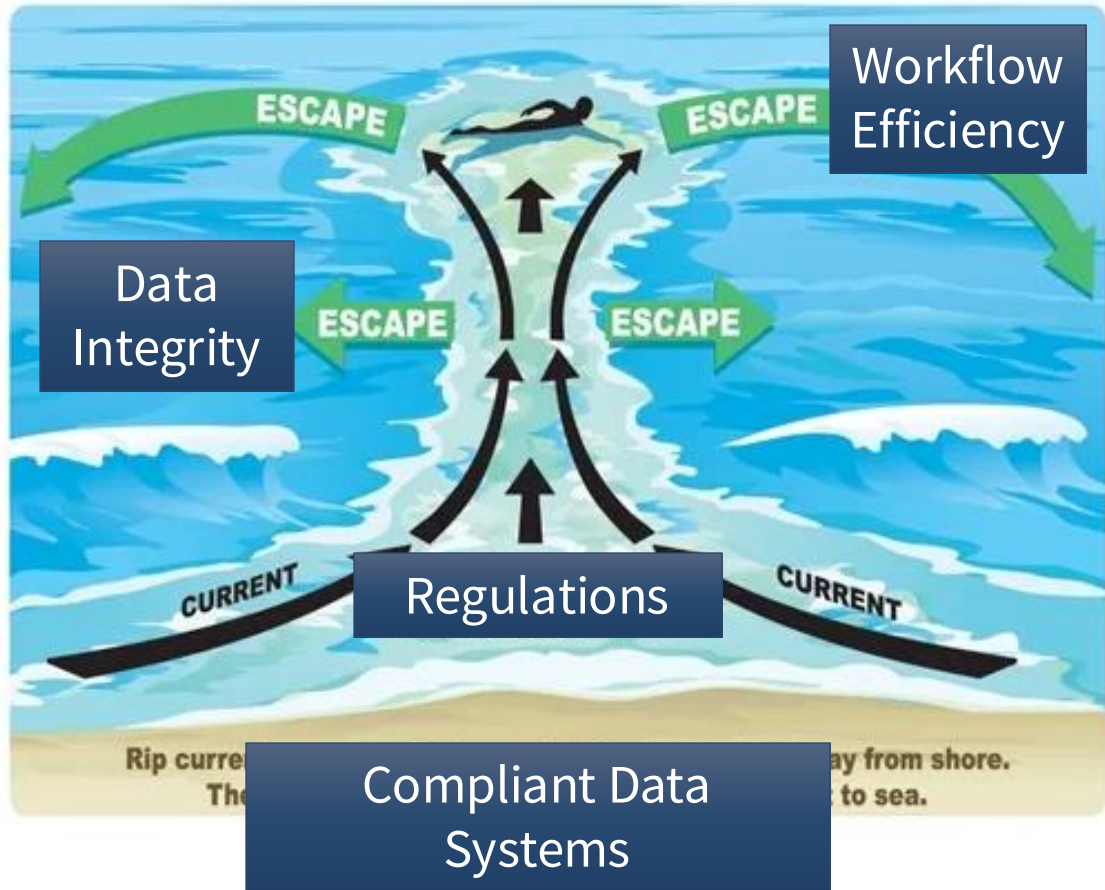
- Regulatory oversight (ICH, FDA, EMA, WHO) ensures the credibility of trial data
- Trials intended for regulatory submission must meet strict compliance requirements
- Not all trials are on this path, but ...
- Beyond meeting regulations, **data matters**
- Every study contributes to global health and advances in healthcare
- Data quality & compliant systems are essential to meaningful research impact





OCEAN BEACH SAFETY

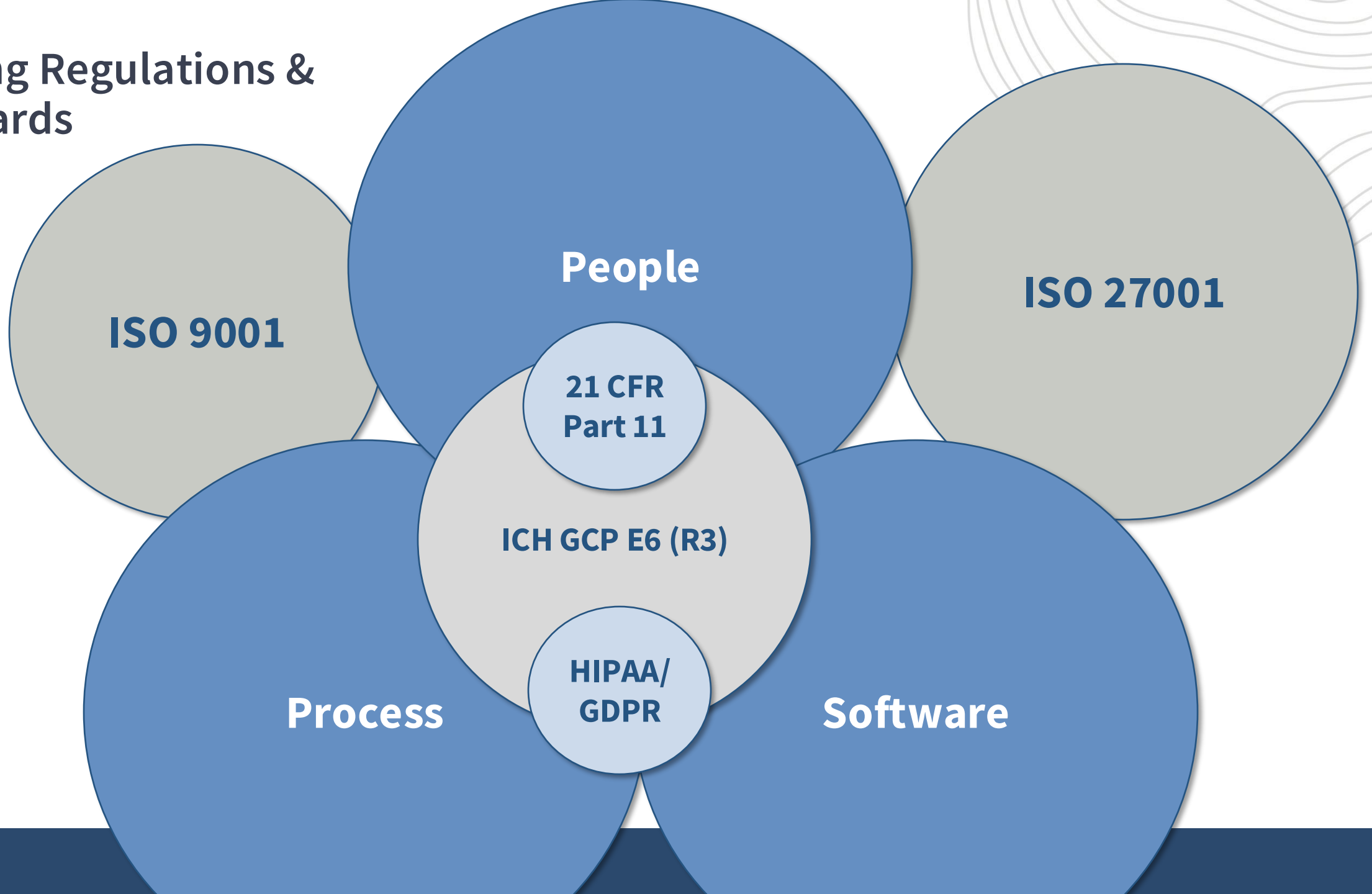
- Recognize the rip current & don't panic
- Don't swim against the current
- Swim at an angle or parallel to shore
- Swim out past the current
- Understand & use the power of the current



CLINICAL RESEARCH

- Recognize **compliance needs** & don't panic
- Don't swim against **regulations**
- Swim at an angle or parallel to **compliance**
- Swim out past **regulations**
- Understand & use the power of **compliance to achieve data integrity & efficiency**

Meeting Regulations & Standards



Common Concerns with Non-Compliant Data Systems

Minimal,
inaccessible, or
non-human-
readable audit trails

Weak data integrity
measures

Lack of scalability
for multi-site trials

No electronic
signature support

Varied
infrastructure

Multiple data
sources

Complex trials

Difficult data export
tools

Ready to graduate to a compliant EDC?

Your research can thrive using free or open-source tools to capture & clean your data – **but only up to a point**

If your data may be used for regulatory submissions – **it's time to graduate** to a system built for compliant clinical data management

A built-for-purpose CDMS allows you to ...

- Comply with regulatory requirements
- Ensure data integrity & security
- Establish clear traceability & governance

Consider the four elements of a compliant EDC

4 Elements of a Compliant EDC



#1: Compliance creates trust



#2: Experience increases speed



#3: Functionality supports flexibility



#4: Planning ensures completeness



#1: Compliance Creates Trust

As a diploma demonstrates education, regulatory compliance shows that your data meets common scientific expectations and will be accepted for regulatory submission.

DFnet's ISO Certifications provide evidence that you and your partners can rely on our systems to withstand scrutiny.

What does compliance require?

Security

- Limiting access to authorized, trained staff
- Ensuring subject privacy
- Eliminating opportunity for fraud
- Tested Business Continuity

Audit Trails

- Linking each data point to a verifiable source
- Including the date, time, and user responsible for each change
- Capturing reasons for change, queries and their resolutions
- Capturing electronic signatures

Validation

Documented evidence that the computerized system (people, hardware, and software) functions as intended

Data Security

- Data encrypted in transit and at rest
- Multi-factor authentication
- Repeat login failures: account lockout & administrator notification
- Physical and logical security at the data center
- Regular patch management and upgrades
- DFnet approach to security:
 - Servers protected in Microsoft Azure
 - Daily backup
 - Azure Site Recovery
 - Regular penetration testing
 - Certified to ISO 27001



Access Controls

- Configurable role-based study access
- Select tools, functionality, reports
- Define data view, edit, delete
- Control access to hidden fields (e.g., blinded data, personal identifiers)
- User access by site, subject, role
- Audit trail of access changes
- Documented approval of user access
- Inactivate user accounts (no delete)

Name: Investigator Status: Active

Description: Save CRFs with eSignature to level 6, save all other CRFs to level 1

Tools & Reports Auto Logout Permissions Restrictions History

DFExplore & API Clients

Server & DFSetup

DFdiscover Reports

Study Reports

DFExplore Views

- Batch Edits
- Dashboard
- Data
- Data - Attach subject document
- Data - Import subject CRFs
- Data - Submit PDF
- Data - with Select
- Image
- Image - Create tasks
- Image - Delete new records
- Image - Raw data entry
- List
- List - Create views
- List - Import Data
- Queries

Server

- Run Report
- Export Data
- Batch Edit checks
- Attach Document
- Import Data

Setup

- View
- Plates
- Edit checks
- Lookup Tables
- Sites
- Missing Map
- Sort Map
- Visit Map
- Conditional Terminations

DFdiscover Reports

- DF_QCView
- DF_QueriesByField
- DF_QueryDataSummary
- DF_QueryOverview
- DF_QueryReport
- DF_QueryStatusTrend
- DF_QueryTimeTrend
- DF_QueryUpdate
- DF_SBallaslog
- DF_SBallasmap
- DF_SBcrfoverview
- DF_SBhistory
- DF_SBschedule
- DF_SBsummary
- DF_SBunexpected
- DF_SiteCRFs

Study Reports

- QC2Excel

Name: Investigator Status: Active

Description: Save CRFs with eSignature to level 6, save all other CRFs to level 1

Tools & Reports Auto Logout Permissions Restrictions History

Get		Show		Modify		Write		Data					Queries					Reasons				
Visits	Plates	Levels	Hidden Fields	Int. Queries	Levels	Levels		C	M	D	L	P	C	M	D	A	R	C	M	D	A	
<input checked="" type="checkbox"/>	ALL	1-2, 4-349, 351-499	ALL	<input type="checkbox"/> Show	<input type="checkbox"/> Show	0-6	1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	50000	350	ALL	<input type="checkbox"/> Show	<input type="checkbox"/> Show	0-6	6	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	99	3	ALL	<input type="checkbox"/> Show	<input type="checkbox"/> Show	0-6	6	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>				<input type="checkbox"/> Show	<input type="checkbox"/> Show			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Configurations Auto Logout Permissions Watermark History

Simplified Detailed history Refresh Filter... Show roles users Save As...

	Date and Time	Who	Change	User Name	Role Name	What Changed	Attribute	Old Value	New Value
72	2024-11-15 17:23:10	james530	grant user	james_ePRO	ePROdata	permission	Status		Active
73						Sites: 99	Sites		99
74						Subjects: 99002	Subjects		99002
75	2024-11-15 08:40:10	yiguo	modify user	yiguo560	unrestricted	permission	Status	Active	Inactive
76						Sites: All			
77						Subjects: All			
78	2024-11-12 16:45:04	calvin	grant user	testuser11256	testrole11256	permission	Status		Active
79						Sites: All	Sites		All
80						Subjects: All	Subjects		All
81	2024-11-12 14:57:59	craig530	grant user	craig530	internal-queries-permission	permission	Status		Active
82						Sites: All	Sites		All
83						Subjects: All	Subjects		All
84	2024-11-12 14:57:59	craig530	revoke user	craig530	Test Data Manager	permission			
85						Sites: All			
86						Subjects: All			

Audit Trail Integrity

- All data modifications must be automatically logged with immutable, time-stamped entries
- Ensures full traceability of changes to prevent data tampering or loss
- Audit trail must contain the “why”
- Focus on human-readability

Page History	
Field: Visit Date	
2020-04-28 14:23:58	lisa entered data "08/MAR/2020"
Field: Were vital signs collected?	
2020-04-28 14:23:58	lisa entered data "Yes"
Field: Weight	
2020-04-28 14:23:58	lisa entered data "165.5"
Field: Weight Unit	
2021-07-27 07:27:20	lisa modified data to "":Missing Value"
	lisa created reason "Other, please specify: Although this weight is likely in pounds, it cannot be confirmed."
2020-04-28 14:23:58	lisa entered data "lb"
Field: Height Not Done	
2020-04-28 14:23:58	lisa entered data "Not Done"
Field: Oral Temperature	
2021-07-27 07:27:20	lisa modified data to "37.5"
	lisa created reason "Data entry error, now corrected."
2020-04-28 14:23:58	lisa entered data "37.2"
Field: Pulse Rate	
2020-04-28 14:23:58	lisa entered data "055.0"
Field: Blood Pressure Not Done	
2020-04-28 14:23:58	lisa entered data "Not Done"
Field: Systolic blood pressure	
2021-07-27 07:24:55	lisa created "Monitor" query with Detail "Please upload source notes to confirm systolic blood pressure." Type "Correction." Use "External"

Times shown in UTC-04:00

OK

Electronic Signatures

- **Authentication:** Unique username and password (or equivalent) per user
- **Access Control:** Role-based permissions ensure only authorized users can sign
- **Signature Binding:** Each signature must be permanently linked to the associated record and cannot be removed or altered
- **Signature Components:** Capture and display signature elements:
 - Full name of the signer
 - Date and time of signing (with time zone)
 - Meaning (reason) of the signature
- **Tamper-Proof:** Signed records must be protected from unauthorized alteration or deletion
- **Audit Trail:** Capture each signature event: who signed, when, and why

This page is eligible for signing

By entering your username and password, you are executing your electronic signature, which is the legally binding equivalent of your handwritten signature. Your electronic signature on this form indicates that you confirm that the information provided is accurate and true, according to site operating procedures and Good Clinical Practice (GCP) guidelines.

Enter password:

Username

Password

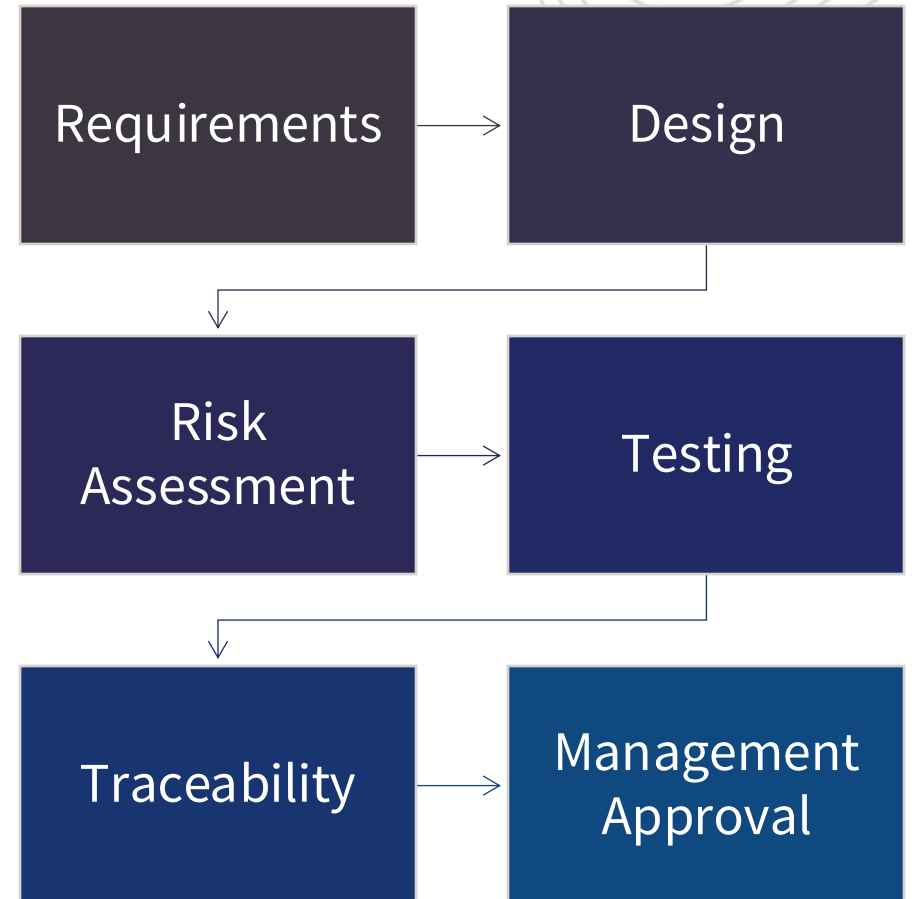
Electronic Signature

Click Save or Final to provide your electronic signature on this record.

Name	Laura Joldersma
Date and Time	2024-09-29 16:51:14 UTC-04:00
Reason for signing	<input checked="" type="radio"/> I approve this data <input type="radio"/> I have reviewed this data <input type="radio"/> I am the author of this data
	Reset

System Validation

- Software must undergo formal validation and periodic review to demonstrate regulatory compliance
 - Emphasis on continuous validation throughout the system lifecycle
- Well-audited package to demonstrate IQ/OQ/PQ validation
- Change control documentation to track system updates and assess their impact on data integrity



#2: Experience Increases Speed

DFnet's expertise helps identify the fastest, most efficient way to collect data

30+ years of experience collecting & managing data in diverse environments

- Electronically transmitting CRF images from Africa to North America since 1997
- Offline EDC via tablets since 2015
- ePRO, secure data input, and export

DFdiscover software supports research organizations around the globe

160+

Clinical Trials
Supported



30

Years in
Global Health



Trusted Partner
of the Global
Health Clinical
Consortium
(GHCC)

Developers of
DFdiscover
Hybrid CDMS
Software

Teams located
in the US,
Canada, and
South Africa



eClinical Solutions
Include EDC
ePRO, and Online
Offline Data
Capture

Studies in
35+
Countries

Spanning

5

Time Zones



DFdiscover,
proven CDMS
solution used by
the VA and NIH-
NIAID for over
20 years

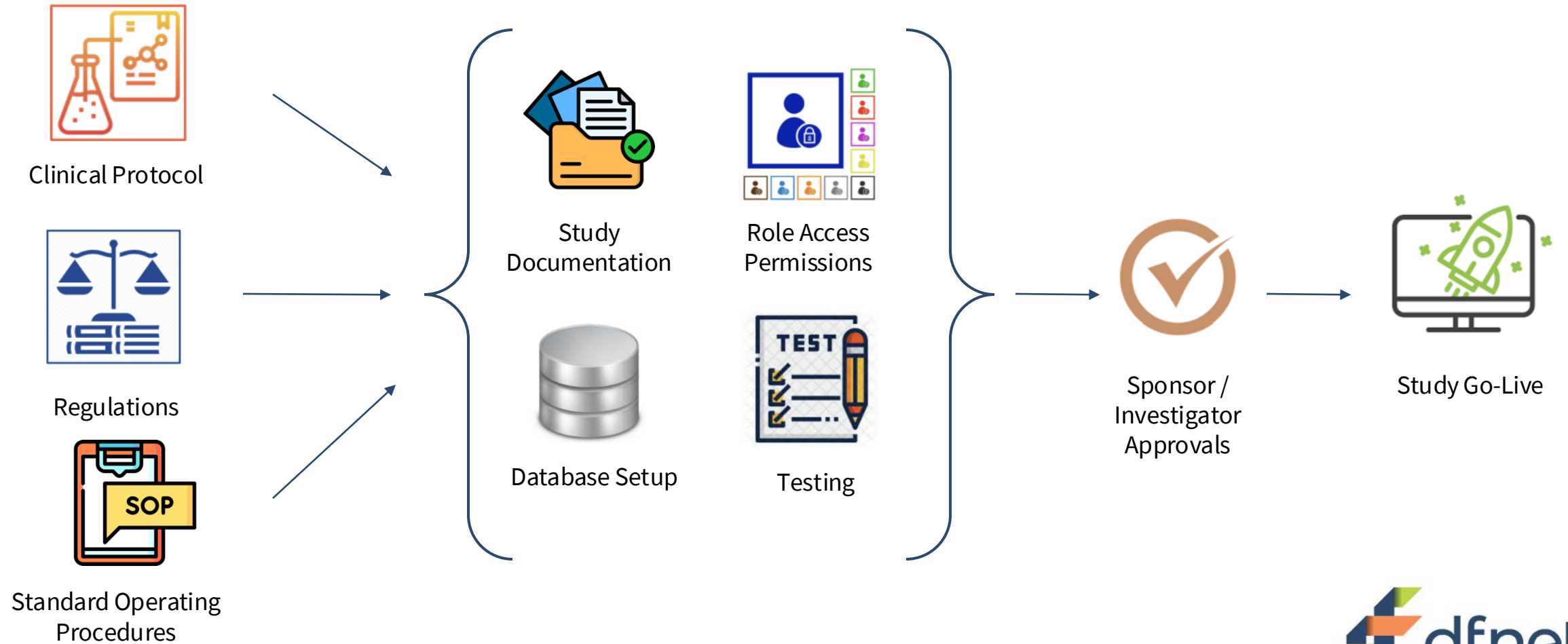


Data
Management &
Data Science
Partners



Better Data. Better Insight. Better Care

Study Initiation → Go-Live



#3: Functionality Supports Flexibility

Choose a CDMS with functionality that meets your study protocol & workflow needs

Capture data from multiple sources in a single system

Collect data on any schedule: Multiple visit cycles, cohorts, early termination

Implement consistency & validation checks in accordance with risk-based, fit-for-purpose principles

Electronic Data Capture

- Enter and update data
- Respond to queries
- Dashboard, reports, listings
- Use any device: laptop, browser, tablet, smartphone
- Data import & export
- Direct data entry or data integrations
- Offline data capture with DFcollect tablet app

The image displays three overlapping screenshots of the DFdiscover software interface. The top-left screenshot shows a 'Protocol Deviation' form for subject 40004, with fields for Visit Number (45001), Subject ID (40004), Date of Deviation (12/NOV/2018), and Study Visit Involved (0280). The top-right screenshot shows a 'Query' window with a table of results, including columns for Category, Status, and Creator. The bottom screenshot shows a dashboard for 'Subject 50001' with a list of visits and a detailed form for '10: Subject Encounter' on 02/FEB/2018. This form includes questions about study visit attendance, adverse events, and new medications, as well as a 'Monitor use only' section for SDV completion.

Offline Data Capture

- **Streamlined:** One system for EDC, ePRO – offline or online
- **Fast:** No extra setup time or separate configuration
- **Full offline support:** Data entry and modification, quality checks, source documents, query resolution, eSignatures
- **Easy updates:** Mid-study changes and protocol amendments pushed automatically to all devices
- **Simple sync:** Conflict resolution for any discrepancies
- **Data loss prevention:** Restore unsaved data after logout
- **Security:** Full encryption to keep on-device data safe

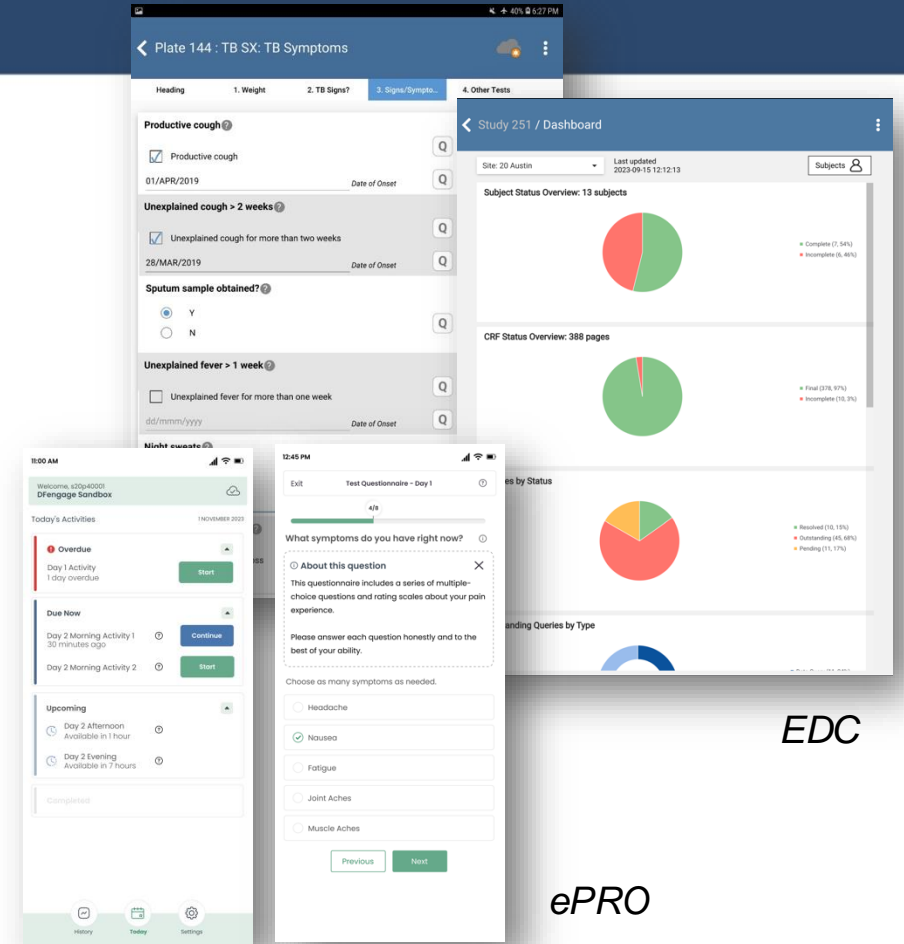
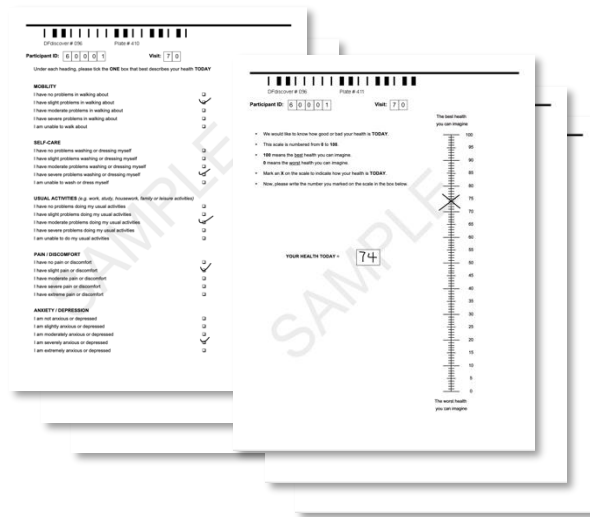
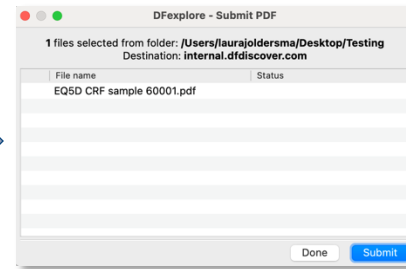
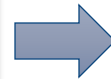


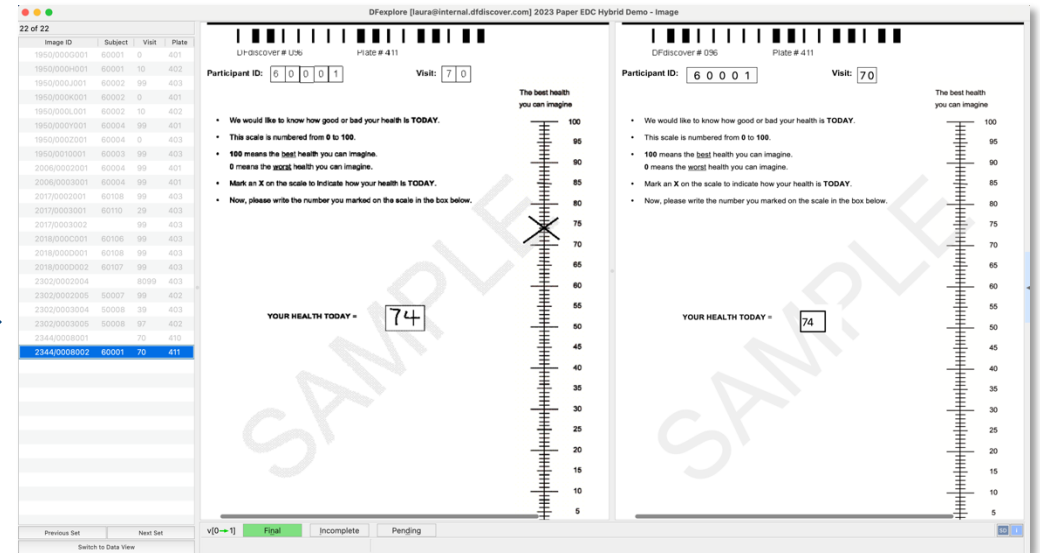
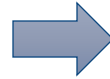
Image-Based Data Capture



Paper CRFs completed
Barcode added in advance



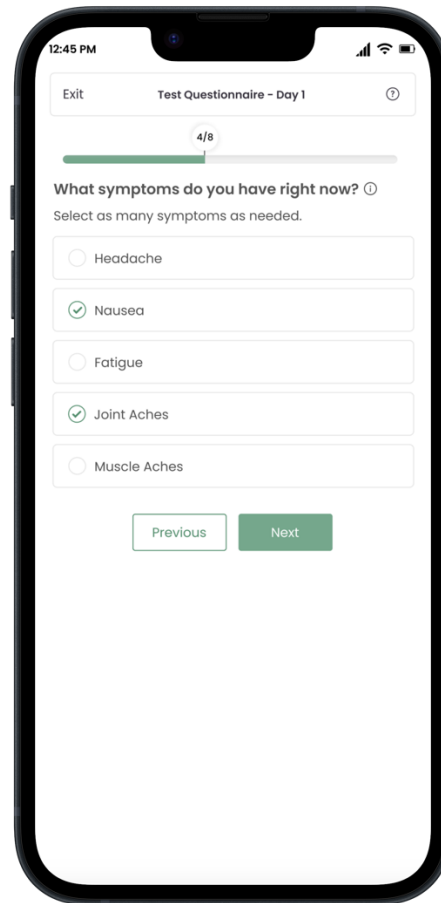
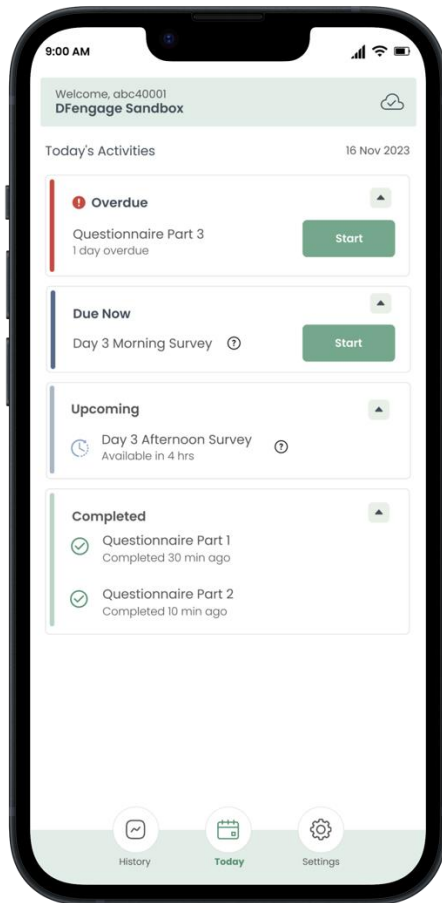
Scanned copy sent via secure
transmission



Data entry assisted by
Optical Character
Recognition (OCR)



Participant Surveys with Integrated ePRO



- Easy-to-use app for study participants
- Collect symptoms, daily outcomes, questionnaires, study diaries, surveys from anywhere, even offline
- Reduce in person visits & phone calls
- Improve data quality & protocol adherence
- Fully integrated with DFdiscover CDMS

eConsent



- Go digital with a secure and compliant eConsent system
- Improve patient experience, reduce paper and data entry burden

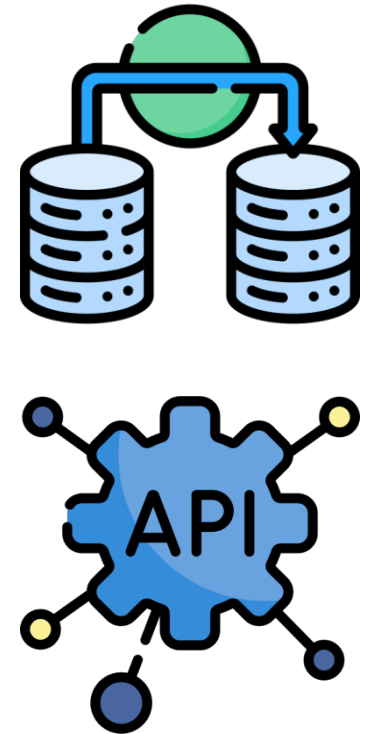
Randomization



- State of the art algorithms reduce sample size without reducing power
- Flexible, anytime access via web, text message, and phone

Data Migration from Existing Systems

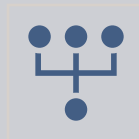
- Import database definition from Excel file
 - Use existing database schema to create new database
- Flexible data import options
 - Self-service data import tool for external data migration with mapping options
 - Powerful backend tools for developing data exchange, transformation, and loading (ETL) processes
- API for integration with external systems



#4: Planning Ensures Completeness



Comprehensive Data Management and Statistical Analysis Plans



Implementation of CDISC standards: CDASH, SDTM, ADaM



Defined study scheduling to quickly identify data gaps



Risk-based oversight to ensure data quality and integrity

Risk-Based Quality Management (RBQM)

- The ability to specify ***the most important data***
- Adoption of real-time data monitoring tools to identify risks and anomalies early and throughout the trial process
- Proactive issue resolution through automated quality control measures
- A compliant EDC provides:
 - Required, essential, and optional fields
 - Required, conditional, and optional visits and CRFs
 - Cycle management, including visit, cycle, and study termination
 - Complete query management with audit trails and documented resolution

Data Management Oversight



Initiation

- Data workflow
- Data validation checks
- CDISC standards
- User acceptance testing
- Query management
- Randomization

Setup

- Subject scheduling
- Email alerts
- Listings & reports
- SAE reconciliation
- Clinical coding
- Source data verification

Management

- Data review meetings
- Data export & transfers
- Lab normal management
- External data integration & reconciliation
- Database lock

Closeout

Data Quality Checks

Queries

Subject 10014 / Visit 0 / Plate 1 / Date of Inform

Monitor

Value: 11/MAR/2025

Detail: According to source documentation initial obtained on 10/MAR/2025, please review.

Reply: Data entry error corrected.

Missing

Value:

Detail: Date of In

Add a query...

? Hemoglobin Result has a value of 36.2, which is inconsistent with our expected legal range of 12.0-17.2. Please verify that this value is correct.

If this is a data entry error, please click '**Fix Now**' to review and make any appropriate changes.

OR

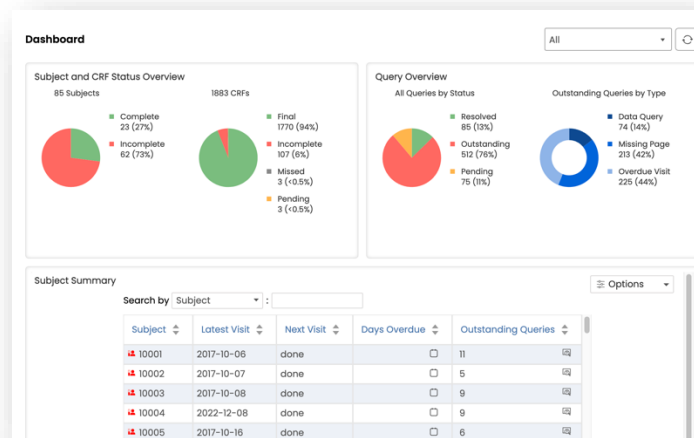
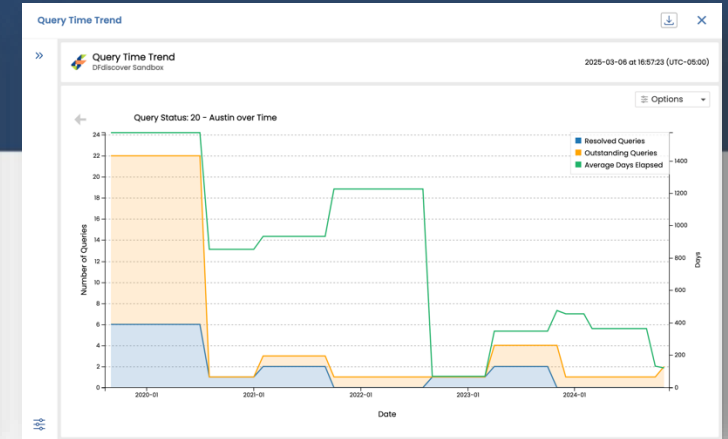
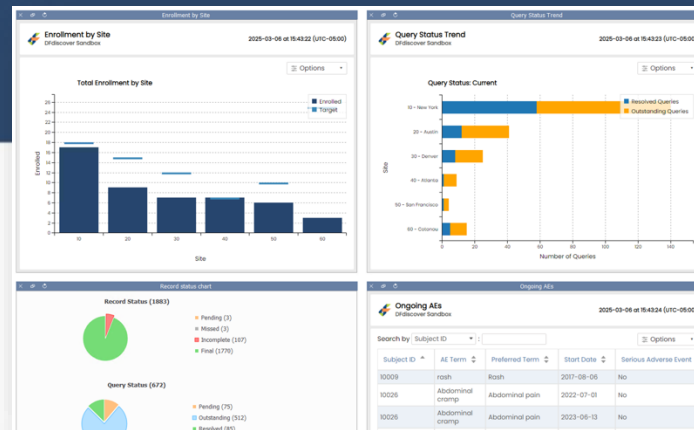
Click '**Reply to Query**' to proceed without a data change, and provide a Reply.

Keys: ID, Visit, Plate Meta: Status, Level, CRF	Variable Edit check	Action	Log Entry
10011, 20, 10 1, 1, 2234R03HB002	VISNAME_010 AutoFillVisName	Change Data	Change VISNAME_010 from blank to Day 2
10013, 560, 10 2, 1, 2234R03HB004	VISNAME_010 AutoFillVisName	Change Data	Change VISNAME_010 from blank to Day 56
10026, 10, 10 2, 1, 2229/000G001	VISNAME_010 AutoFillVisName	Change Data	Change VISNAME_010 from blank to Day 1
10026, 10, 10 2, 1, 2229/000G001	SDV_010 SDVChange2	Change Data	Change SDV_010 from blank to 0
10026, 10, 10 2, 1, 2229/000G001	SDV_010 SDVChange2	Add Reason	Reason for change text added to SDV_010: Set by edit check SDVChange2
10027, 10, 10 2, 1, 2229/000D001	VISNAME_010 AutoFillVisName	Change Data	Change VISNAME_010 from blank to Day 1
10027, 10, 10 2, 1, 2229/000D001	SDV_010 SDVChange2	Change Data	Change SDV_010 from blank to 0
10027, 10, 10 2, 1, 2229/000D001	SDV_010 SDVChange2	Add Reason	Reason for change text added to SDV_010: Set by edit check SDVChange2
20006, 10, 10 1, 1, 1937R0002071	SEEXPL g_OnlyReqIf(-1,2)	Add query	external fax/refax Query added for missing value to: SEEXPL status=new Query: Please review. Because 1. Did subject attend study visit? is marked 'No', if no, provide
30006, 350, 10 2, 1, 1938R000N003	SEEXPL g_OnlyReqIf(-1,2)	Add query	external fax/refax Query added for missing value to: SEEXPL status=new Query: Please review. Because 1. Did subject attend study visit? is marked 'No', if no, provide
40001, 0, 10 1, 1, 1943R0005004	SECMGP1 g_OnlyReqIf(-1,1)	Add query	external fax/refax Query added for missing value to: SECMGP1 status=new Query: Please review. Because 3. Were any new CM's reported at visit is marked 'Yes', CM P.

- Built-in query management
- Interactive data checks during data entry
 - Current field (univariate)
 - Cross-field (multivariate): same page, cross-page, cross-visit
- Batch checks ensure no data quality issues are missed

Reporting

- Customizable dashboard
- Charts & graphs
- Data listings
- Interactive with CRF data
- Export as HTML and Excel
- Flexible export tools



Concomitant Medications

Subject ID	Medication or Therapy Name	Indication	Start Date	End Date	Ongoing	Dose	Dose Unit
10001	BENLYN COUGH	COUGH	2017-11-01	2017-11-05	No	25	MG
10001	aspirin	HEADACHE	2017-10-31	2017-10-31	No	100	MG
10002	ALDOMIN	HYPERTENSION	2019-01-03		Yes	250	MG
10002	MULTI-VITAMIN	GENERAL HEALTH	2019-01-03		Yes	1	PILL
10002	ALOSETRON	IBS	2019-01-05	2019-01-06	No	0.5	MG
10003	VITAMIN C	GENERAL HEALTH	2019-01-05		Yes	50	MG
10005	ZOLMITRIPTAN	HEADACHE	2019-01-10	2019-01-11	No	2.5	MG
10007	DAYQUIL	SORE THROAT	2019-01-28	2019-02-02	No	325	MG
10009	MELATONIN	SLEEP ISSUES	2018-12-31		Yes	5	MG
10018	Ibuprofen	HEADACHE	2021-04-06	2021-04-07	No		
20001	AMOXICILLIN	BRONCHITIS	2019-01-02	2019-01-07	No	500	MG
20002	Ibuprofen	TEST	2022-12-13		Yes	_U	_U
20007	TRAZODONE	INSOMNIA	2019-01-12	2019-03-01	No	50	MG
20008	MIRENA IUD	BIRTH CONTROL	2017-12-09		Yes	1	UNIT
40001	clonidine	DEPRESSION/DISSOCIATION	2007-01-20		Yes	15	MG
40002	vicodin	DEGENERATIVE DISC DISEASE	2017-04-04		Yes	50	MG

Visit Scheduling

← Subject 10032 - Schedule Info

Search by Visit :

Site	Subject	Visit	Name	Schedule Date	Complete Date	Days Off-Schedule	Days Overdue	Status
10	10032	99	Screening	2024-04-09	2024-04-09	0	0	final
10	10032	0	Enrollment/Vaccination #1	2024-04-10	2024-04-10	0	0	final
10	10032	10	Day 1	2024-04-11	2024-04-11	0	0	final
10	10032	20	Day 2	2024-04-12	2024-04-12	0	0	final
10	10032	30	Day 3	2024-04-13	2024-04-13	0	0	final
10	10032	70	Day 7	2024-04-17		0	328	
10	10032	280	Vaccination #2	2024-05-08		0	307	
10	10032	310	Day 31	2024-05-11		0	304	
10	10032	350	Day 35	2024-05-15		0	300	
10	10032	560	Day 56	2024-06-05		0	279	
10	10032	19001	MH Page 01			0	0	final
10	10032	29001	MH Log Page 01			0	0	
10	10032	20001	AE Page 01			0	0	incomplete
10	10032	30001	CM Page 01			0	0	incomplete
10	10032	45001	PD Page 01			0	0	
10	10032	50000	Termination			0	0	

30012

- > Screening
- > Enrollment/Vaccination #1
- > Day 1
- > Day 2
- > Day 3
- > Day 7
- > Vaccination #2

Enrolled subject

Study visits displayed,
overdue visits in red

10043

- > Screening
- > Termination

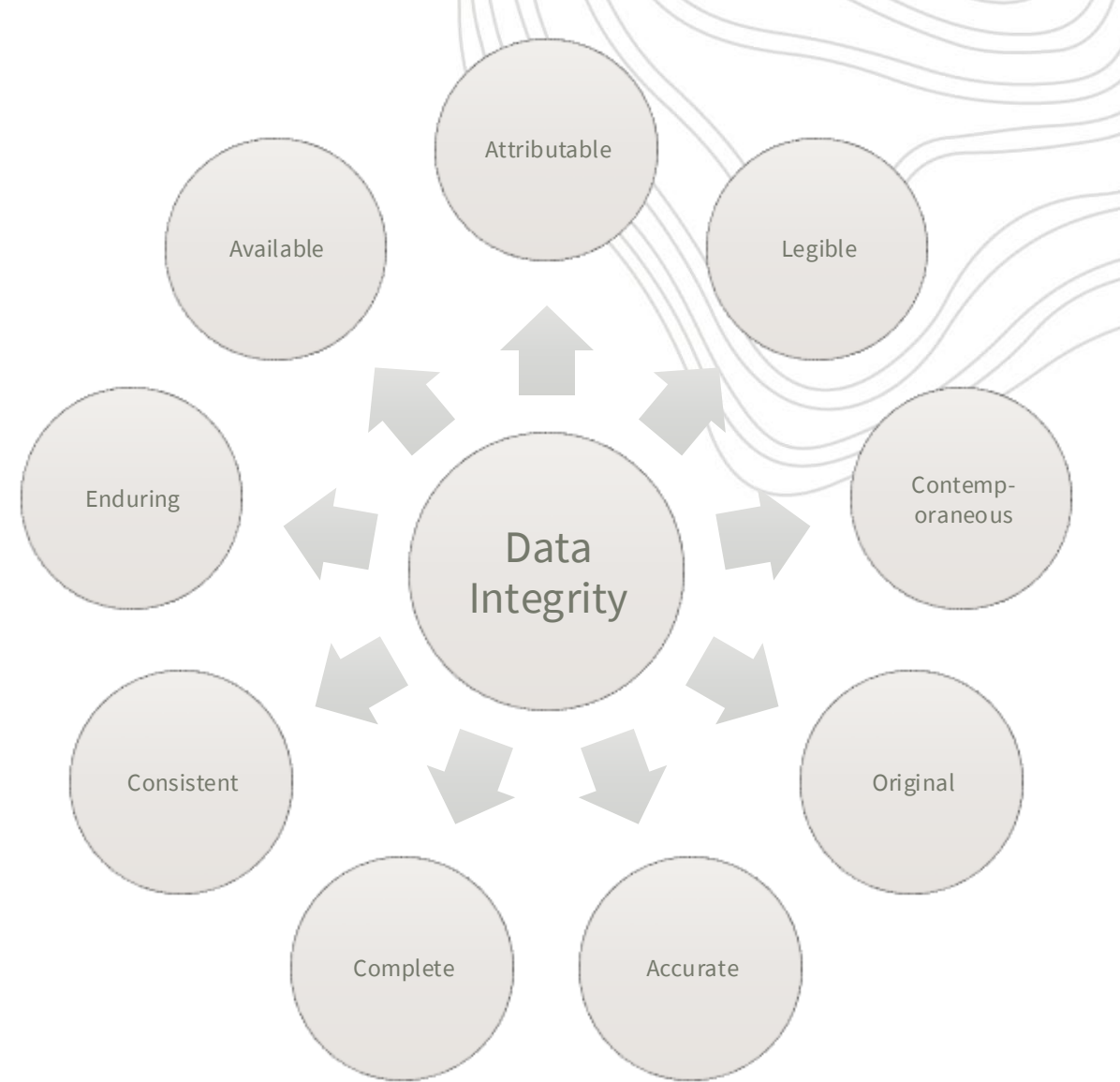
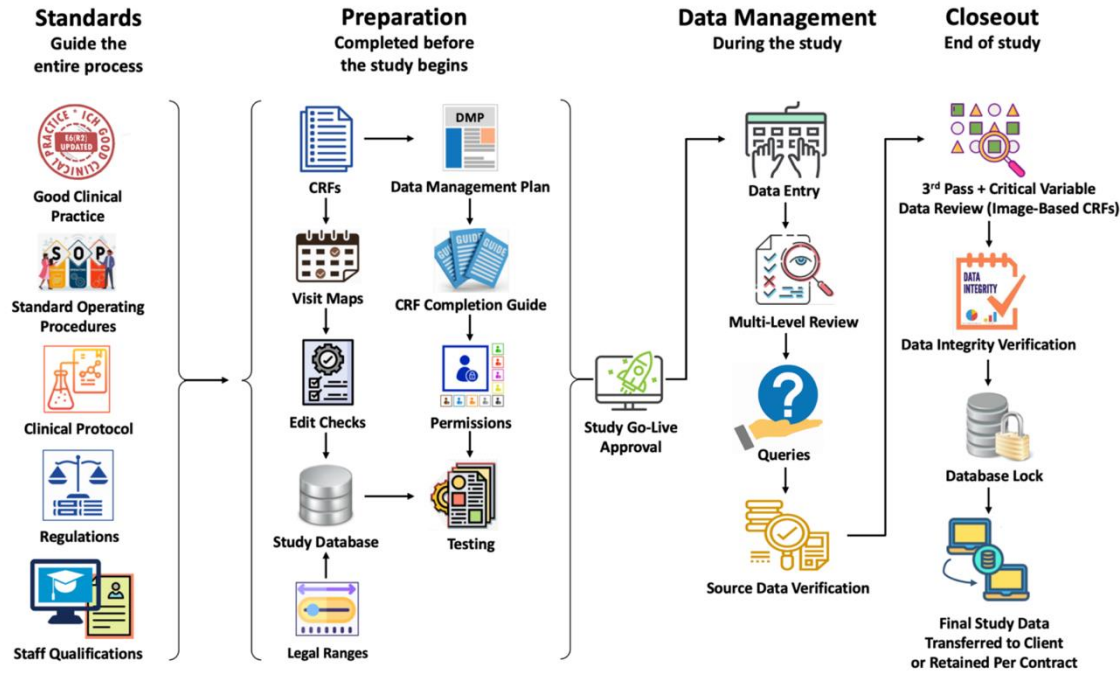
Screen failure

No study visits displayed

- Apply complex visit scheduling and CRF completion requirements
- Automated queries for overdue visits and missing pages
- Only display relevant visits and CRFs in the subject binder

Assuring Data Quality

STRATEGIES TO PRODUCE ALCOA++ DATA



It's time to graduate to a compliant EDC system when you...

- Begin to prepare for regulatory submissions
- Anticipate increased oversight
 - Sponsor / investigator expectations
 - Research grant / funding requirements
- Need to manage clinical complexity
 - Varied data sources (paper, ePRO, lab data)
 - Multiple sites, treatment cycles, cohorts
 - Adaptive randomization
- Want to build research data infrastructure for the long-term



Q & A

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