

# IBM Clinical Development

Key solutions for more  
efficient clinical research

# IBM Clinical Development

By collaborating with industry experts on advanced technologies, we find new ways to help clinicians improve patients' lives.

IBM's highlighted solutions reside in a security-rich cloud environment—home for capturing, managing and analyzing clinical study data with control, accuracy and confidence.

These solutions lay the groundwork for further integration with IBM® Watson® cognitive technology.

IBM's development efforts synchronize with the ability of Watson™ to retrieve vast amounts of data from key medical sources while working to protect patient privacy. Watson allows clinical, research and social health information to be analyzed in ways that would ideally include patient populations that have never been studied.

Figure 1: IBM Clinical Development has a solid track record. Statistics obtained September 2018.

|          |                     |
|----------|---------------------|
| 2,000+   | studies             |
| 775,000+ | subjects            |
| 25       | Therapeutic areas   |
| 30+      | languages           |
| 200      | partners            |
| 24x7x365 | support             |
| >20      | years of experience |

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## Platform overview

IBM Clinical Development—a growing platform from IBM Watson Health—is helping to transform clinical research. With cloud-based electronic data capture (EDC) at its core, IBM Clinical Development addresses clinical studies in a unified, flexible and collaborative manner. IBM strives to reduce administrative burden on clinical centers and engage patients in their journeys toward healthy lives.

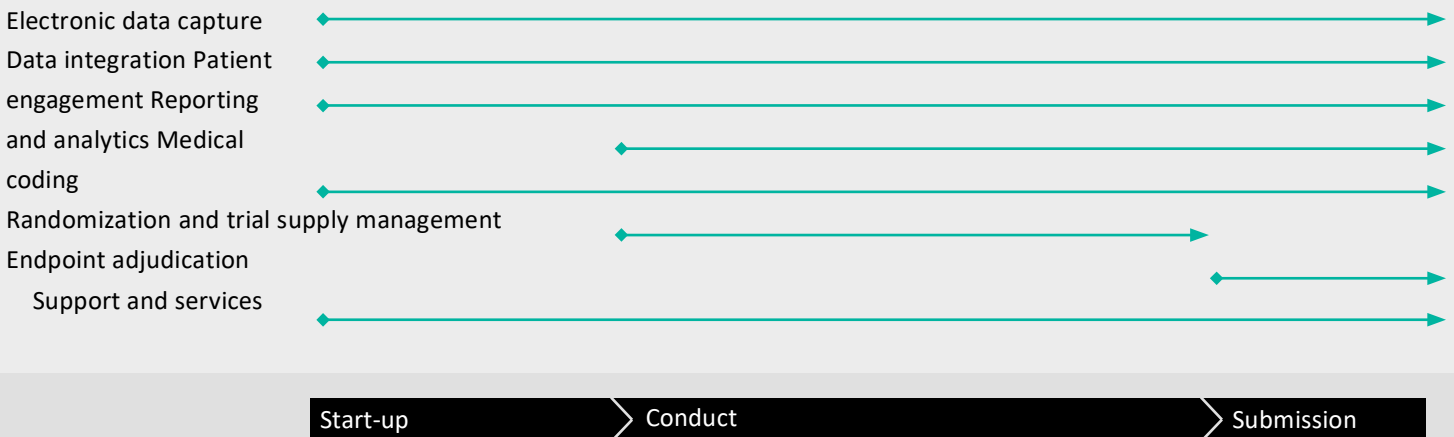
IBM Clinical Development supports a variety of clinical study types, whether focused on a medical device or a therapeutic area in a trial during early to late phases. This scalability is reflected in both the functional aspects of a study and the costs.

IBM teams, from study designers to technical and compliance experts, have deep domain understanding of what's critical to the success of a clinical trial.

IBM Watson Health also provides concise training that enables users to work independently. Users can build and launch studies with skill and confidence should they choose a self-service approach. Full-service builds, support and implementation are also available and managed by IBM expert solution teams.

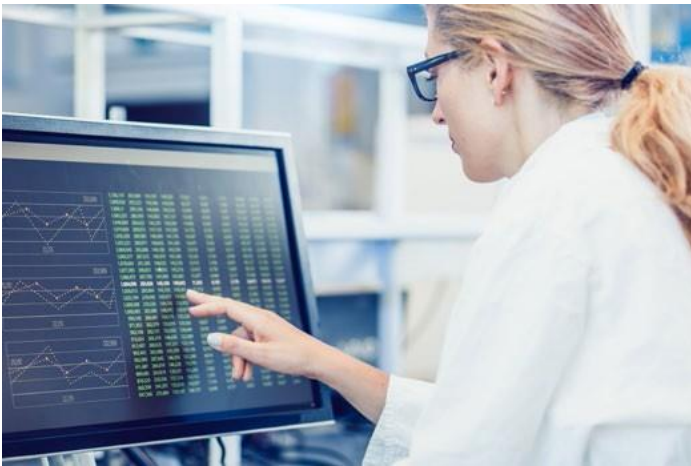
IBM Watson Health solutions can adapt to user needs. The platform serves the entire study, from startup to submission as shown in Figure 2. Users control every study detail, whether managed by themselves after an initial training process or by clinical experts at IBM Watson Health. Users may also choose only those solutions that are valuable to their specific needs at specific times. The following pages describe these solutions.

Figure 2: IBM Clinical Development serves the whole study.



# Electronic data capture

Security-rich cloud that serves diverse users with unique requirements



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IBM Clinical Development offers a unified cloud-based EDC system, serving a broad range of user types and offering full- and self-service opportunities. For at-a-glance convenience, this solution—considered the core of the IBM Clinical Development platform—is summarized according to features users value most.

### **Adaptable for:** Studies in any

- Therapeutic area
- Trial category, including medical device
- Study phase, early to late

### **Research from**

- Company sponsors
- Clinical research organizations
- Academic research organizations
- Investigator-driven programs

### **Functions that**

- Span studies from startup to submission
- Serve specific requirements

### **Accessible using:**

- Cloud-based technology
- Single URL entry point
- Role-based dashboard and visual metrics
- Various browsers and devices
- Global language translations

### **Security-rich and regulated using:**

- HIPAA protections
- Enterprise-class firewalls
- Role-based permissions
- Backup and disaster recovery

### **Efficient for:**

- Building and beginning studies within days
- Requiring no servers or hardware from user sites
- Providing in-house support teams around the clock
- Training users to be self-sufficient
- Providing certified designers



**Solution driven for the following capabilities, described later in detail**

**Data integration**

Automate processes to reduce laborious data entry, upload data directly through web services and application programming interfaces (APIs), and map to case reports.

**Patient engagement**

Employ electronic patient-reported outcome (ePRO) technologies, including web and mobile device (iOS + Android-enabled) applications, to strengthen patient participation and communications with medical teams.

**Reporting and analytics**

Design and build standard and custom reports from virtually any field or metadata source and uncover meaning through analytic reporting.

**Medical coding**

Use a single system that's integrated with EDC and current dictionaries to code and make discoveries through analytic reporting with the eventual Cognitive Coding integration with Watson AI.

**Randomization and trial supply management**

Define treatment options, track inventory and shipments, and dispense to subjects, with patient records and data exports, always matching tracking details.

**Endpoint adjudication**

Streamline critical workflows inherent to the adjudication process; capture all required endpoint details and source documents for immediate review and perform adjudicator assessments.

**Support and services**

Rely on IBM experts to design, train and support user teams for a range of services, from full-service study build and project management to customized manuals and user site training videos.

- Additional features**
- Custom-made case report forms and study visit schedules
  - System edit checks
  - Complex query functions
  - Field, page and visit dynamics
  - Configurable data review and cleaning workflows
  - Multiple subject revision moves
  - Conditional alerts and notifications, email and text
  - On-demand data exports, including SAS, CSV, XML, Microsoft Access and tab delimited
  - On-demand study documentation, design document, subject PDFs
  - Automated data archive, post-closeout on-demand data access
  - Seamless query task management
  - Team management capabilities
  - Security-rich hosting

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### Support center

- Trained professionals available 24 hours a day, 365 days a year
- Help with general questions, study design and troubleshooting
- Communicate through phone, email or chat

### Technology infrastructure Security

- Security-rich file transport with 2048-bit SSL/TLS encryption
- Redundant firewalls and B2B VPNs
- Tier II, SSAE 16-certified data center; rated for Category 4 hurricanes

### Availability

- 99 percent business hour availability
- 24x7x365 technical support

### Continuity

- Hourly data replication to disaster recovery site
- Disk-based, daily local data backups
- Offsite tape backups; FIPS 140-2 compliant

### Source data verification

The source data verification tool within IBM Clinical Development is a standard feature that enables any data collection field to be labeled as source data verified within the study design. Standard reports assist those performing source data verification to manage and track their workload, and navigate from report to form.

### Compliance

IBM Clinical Development assists the industry in the United States, the European Union and Japan with regulatory submissions by providing clinical study solutions that support the standardization and harmonization of:

- Serious adverse events and safety reporting
- Structure and content of clinical study reports
- Statistical reporting

During the development, deployment and management of solutions offered by IBM Clinical Development, applicable regulations and FDA guidelines are stringently followed. The following table summarizes IBM Clinical Development compliance.

| Regulations   | FDA guidelines   |
|---|--|
| Support to clients  |  |
| <ul style="list-style-type: none"><li>— 21 CFR Part 11, 50, 54 312, 820</li><li>— 45 CFR Part 162, 164</li><li>— EU GMP 11</li></ul>  | <ul style="list-style-type: none"><li>— Computerized systems used in clinical trials</li><li>— Investigator responsibility</li></ul> |
| Operational compliance  |  |
| <ul style="list-style-type: none"><li>— 21 CFR Part 11, 820</li><li>— EU GMP 11</li><li>— 45 CFR Part 164</li><li>— ISO 9001</li><li>— ICH E6</li><li>— Local and state</li><li>— Privacy shield; certified</li></ul> | <ul style="list-style-type: none"><li>— General principals of software validation</li></ul>  |

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# Data integration Data migration technology that automates processes and reduces hands-on time

## Highlights

- Streamlined timeframes for data imports
- Automated collection of single, recurring and rescue study clinical data imports
- Training program for immediate and effective use of technology

The IBM data integration solution enables timely, automatic integration of data from diverse sources, minimizing data entry and maximizing study team efficiency. An established in-house training program teaches users to build studies and control data integration.

## API services

Data for clinical studies is not always captured digitally. Some sponsors use multiple vendors to collect all the needed information. API services within IBM Clinical Development enable data to be added to the study's EDC without performing data entry. This data can include central lab results that can be provided electronically. Such information is then imported into the system and integrated with existing study data.

## Value added

- Integrate clinical data, query management, metadata, study design details and more.
- Monitor studies and automate the use of imports, increasing study team efficiency.
- Add, update and retrieve data through representational state transfer (REST) APIs.

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## Self-service data migrator

API services typically require a level of programming that most users don't have. IBM's data migrator tool addresses this issue. This resource provides non-programmers with the tools to map, filter, format, test, schedule and monitor import jobs through an intuitive point-and-click interface. The interface greatly reduces time and handoffs when adding data to one-time or recurring imports. A variety of system integrations—from lab imports, endpoint adjudication and medical coding management to rescue studies—can benefit daily from the data migrator tool.

### Value added

- Eliminate custom development and replace with point-and-click data mappings.
- Reduce quality assurance (QA) time through design integration.
- Deploy studies quickly, without involving the IT team.
- Create on-demand or scheduled and recurring import jobs.
- Reduce timelines for data imports.

## Full-service support

API services and data migrator can also be performed and maintained by expert teams at IBM Watson Health.

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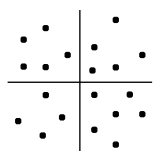




### User experience

During one data integration workshop, the team from IBM Clinical Development trained and certified users on the data migrator tool and created integrations for two studies— that’s two studies’ worth of data and eight certified trainees in four days.

After the workshop, 90 percent of all data from both studies had been mapped, and the user was able to test the data integration within a few days. Both studies completed the integrations in IBM Clinical Development within two months of the workshop.



**2 million data points**  
imported within  
**4 days**

### Study build training program

This program provides facilitated training on the core data integration capabilities of IBM Clinical Development for up to six designers. Participants learn to master the core data migration tool and functions using a provided sample study, or the participant’s actual or sample study. It’s common that trainees also perform subsequent user acceptance testing (UAT) of import.

### Value added

- Import a wide variety of data types into IBM Clinical Development.
- Provide the training needed to build a study using actual study requirements.
- Utilize sophisticated storage of expressions and libraries for ease of cloning across studies.
- Accept file formats, such as .csv, .txt, .xls, and .xlsx, with a variety of standard or customized delimiters.
- Retrieve files from various sources at set times.

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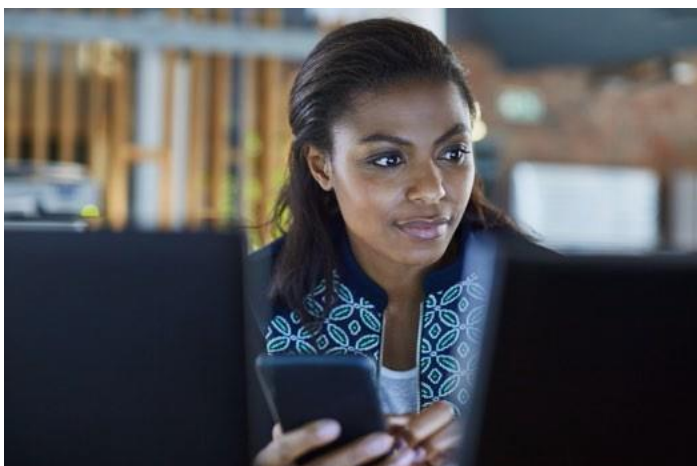
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# Patient engagement

## Tools that help patients share information securely

### Highlights

- Questionnaires can be built clearly and are automatically rendered in both web and mobile applications.
- Data comes directly from the patients via any desktop or iOS/Android-enabled device.
- Patients engage in their language of choice.



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Patient participation and maximized capture of ePROs are essential to clinical study success and lead to improvements in patient-clinician communication, patient satisfaction, symptom management and control, and quality of life.

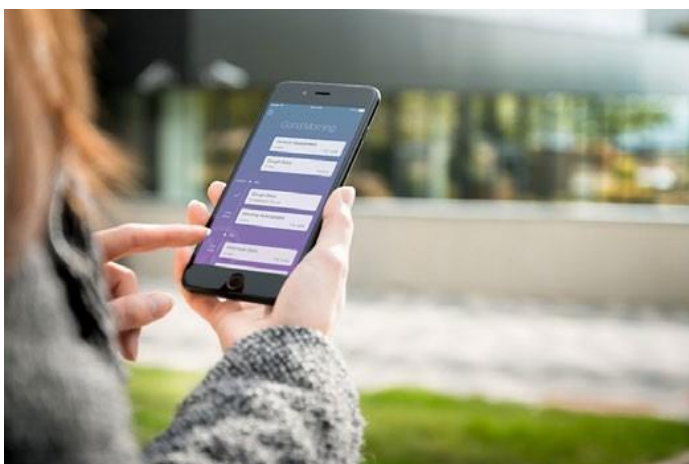
IBM provides ePRO technology that replaces conventional reporting methods and allows patients to share important information with caregivers at any time. With this immediate connectivity, typical overhead requirements are often unnecessary. Patient populations, once thought inaccessible, can now participate easily in timely studies.

### ePRO

- Patients may use computers, tablets or smartphones.
- Patients can report daily healthcare, from symptom details to treatment regimens.
- Patients enter diary information in a security-rich cloud environment.
- A web interface guides patients through the reporting process.
- Physicians can review newly added information immediately.
- Patients can provide feedback on products and procedures.
- Forms may be built and launched within hours.

### Value added

- Rapid access to primary efficacy data from patient entries
- Informed decision-making through evaluation of on-demand source data
- Improved data accuracy regarding treatment effects known only to the patient
- Reduced costs with respect to data cleaning
- Earlier discovery of adverse events
- Elimination of double data entry and steps to decipher handwriting
- Validation of data through a single database in multilingual, global studies
- Support for quality of life, such as sf 12 and sf 36, and other templates
- Reliable data across different therapies, populations and geographies



### IBM My Clinical Diary

[The IBM My Clinical Diary](#) mobile application is designed for participants in active studies and available for iPhone and Android in 30 languages. The data submitted through this application is directly stored in IBM Clinical Development, and no imports or exports are required. As a security-rich system, password and security questions, as well as confidential details, are not stored on the device.

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### Additional features of ePRO

#### Design

One questionnaire build for multiple interfaces

#### User-friendly interaction

Simple, one-time setup; large fonts, graphical cues, such as alert icons, color-coded sections; common query formats and conversational language; single- and multi-question views; interactive voice response (IVR) and interactive web response (IWR) functions

#### Practical help

Built-in user tips to help minimize call center inquiries

#### Flexible questionnaire

Pathing features to guide users through relevant questions only

#### Diverse query formats

Broad range of response forms, including drop-down lists, visual analogue scales (VASs), radio buttons, multi-select buttons and free-text fields

#### Activity-based availability

Specific time and date windows set by designers for diaries to remain active, for example, available every morning for a certain amount of days

#### Preset completion rules

Patients may complete diaries once only, once a day, unlimited number of times, or within specific designated limits

# Reporting and analytics

A concise and clear summary of data that helps capture new insights

## Highlights

- Intuitive usability, with Advanced Reporting powered by IBM Cognos
- Standard-to-complex reporting capabilities
- Build custom reports with personalized ad-hoc reporting
- Training to build reports

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Reporting options range from industry-standard reports to insights derived using the latest advancements in analytics. Our powerful reporting capability, Smart Reports, is powered by IBM Cognos Analytics and helps to create single- and cross-study reports across data sets to facilitate high-level analyses and decision-making. Smart Reports enables researchers to discover new patterns and relationships that would not be obvious in other reporting systems.

### Analytic reporting

Smart reports powered by Cognos presents data as a visual story so users can understand and draw inferences at a glance.

### Standard reporting

Standard reports are configurable to meet the specific needs of each study. The standard report tool can retrieve data from any field, as well as related metadata and use the data to build standard reports. Options include reports from more than 20 report templates and others that represent data in its complexity.

### Design training

IBM Cognos training is available to enhance your reporting and visualization expertise.



## Smart Reports

### Advanced reporting powered by IBM Cognos.

Integrated for seamless reporting with IBM Clinical Development

- Customized for clinical researchers
- Single sign-on eliminates the need for multiple logins
- Reports reviewed in IBM Clinical Development for direct download
- Data warehouse refreshes every 30 minutes, providing up-to-date data and reporting
- Streamlined navigation from multistudy, aggregated data to patient-specific data points
- Cross-study reporting to compare data and performance across sites and patient populations
- Structured query language (SQL) and advanced calculation for complex reporting
- Advanced expression editor for aggregations and calculations
- Ability to drag data columns into visualizations with minimal configuration
- Visualization options include tree maps, geolocation charts and bubble plots
- Designers can add roles and site permissions; data and reports are available to appropriate users only

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# Medical coding Uniform coding among studies and sites, and analytical reporting

## Highlights

- Single-system consistency for all users with roles that are permissions based and flexible
- Up-to-date dictionaries with on-demand up-versioning
- Ease-of-analysis coding reports that enable new medical insights

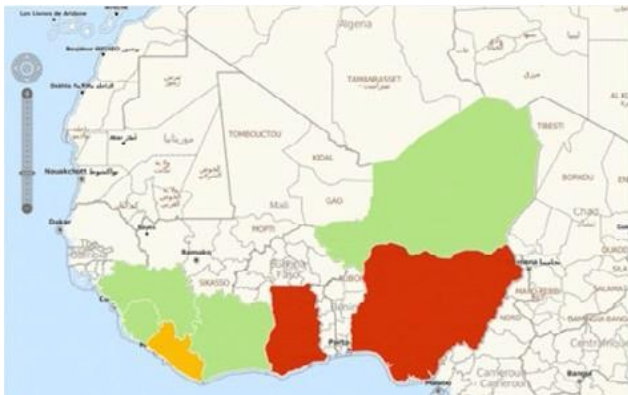


Figure 4: Combining medical coding, site locations and advanced reporting creates compelling visual charts for representing and identifying potential signals within a patient population.

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IBM Clinical Development offers medical coding features that go beyond stand-alone service, using trial data and management workflow to give users more power. Standard dictionary updates provide a complete and clear process for all coding procedures. Data retrieved by EDC and coded within the medical coding solution is further enhanced by exclusive reporting features in Smart Reports, designed to allow researchers to more quickly detect signals and discover new linkages and patterns. The future of this feature will assist in automatically coding adverse events with the integration of Watson AI.

## Solution features

- Draw on EDC for data review, queries and other study tasks.
- Bring important contextual data immediately to the forefront to streamline coding and enhance auto-coding coverage.
- Minimize the additional tracking and storage of files.
- Minimize errors made when using multiple coding systems.
- Batch and view counts at a glance.
- Simplify work flows and create customized views and listings.
- View actionable options more quickly to help make better-informed decisions.
- Designate verbatims before or during the live study.
- Assign different roles with distinct permissions to different sets of users.





### Dictionary continuity

- Access new or legacy versions of MedDRA and WHODrug dictionaries for easy up-versioning, a valuable feature for longer studies.
- Eliminate dictionary maintenance by managing the addition of new versions to the system.
- Help ensure codes align with FDA requirements through updated dictionaries.
- Check entries against dictionary and approved study coding using the auto-coding feature.
- Import synonym and auto-coding rules between study databases to maintain consistency and reduce coding efforts.

Enhancements are typically released every six weeks. Industry-standard dictionaries are maintained and updated for users biannually.

### Watson for Medical Coding

With future integration of Watson AI, our platform will assist Medical Coders- helping to reduce time spend on omission coding. Ultimately advising to improve accuracy and consistency of coding adverse events.

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# Randomization and trial supply management

Processes that provide help to patients swiftly and efficiently

## Highlights

- EDC harmonizes with study operations and supply transfer.
- A clear, interactive web environment simplifies study processes.
- Users define stratification and assign treatment groups.
- Streamlined management throughout the entire distribution, tracking and return process on one integrated interface

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IBM Clinical Development encompasses randomization and dispensing capabilities that are designed, configured and updated quickly based on study requirements and without the need for programmers. One dashboard houses randomization and data capture needs so users don't have to purchase expensive, customized connections. The solution relies on specialized research and development that prepare the software system to generate data that's linkable to each patient. The goal is to attain a more secure and error-free environment that's sensitive to the necessary steps of subject unblinding during clinical studies.

## Manage randomization

Randomization assignments may be managed using a wizard-driven user interface, with options to randomize subjects automatically or manually. Stratify by data point, site, study or other criteria. Randomize from a single, static list or dynamically.

This system, which includes the IWR feature, allows users to define stratification factors to select and assign subjects to randomized treatment groups. Users can also assign randomization records to subjects directly in the IBM Clinical Development EDC and include the information in the same data export.

Users can randomize to any schema and randomize data remotely using the IBM Clinical Development Study Connect mobile application, available in the Apple Store.







## Inventory management, dispensing and returns

This system provides real-time status of research inventory, helping coordinate the entire tracking, dispensing and return process. With built-in system checks and guidance, users can:

- Define treatment options
- Enter, manage and track inventory in shipments and at the site
- Dispense to subjects
- Include dispensing details and shipping information from depot to subject in the study data exports associated with each subject's record
- Coordinate the entire distribution, tracking and return process using an integrated interface that provides an overview of research inventory
- Track shipments from depot to depot and manage stock across sites through an auto-resupply option

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# Endpoint adjudication

## Streamlining your adjudication workflow for better science

### Highlights

- Electronic capture of source documentation and endpoint details
- Efficient online access and easy workflow for sites, adjudicators and coordinators
- Paperless workflow coordination and online dossier creation to prevent lost documents
- Significantly reduces study timelines

Endpoint adjudication tools and workflows are an inherent part of the core EDC offered by IBM Clinical Development. Site coordinators and adjudicators have immediate online access to content they need. With point-and-click logic, further development and programming are unnecessary, and users achieve full independence once adopted.

At the click of a button, a dossier is compiled from all endpoint details and source documents, such as death reports. Endpoint cases progress through the entire adjudication process automatically.

The system handles virtually any size study and essentially any number of sites and events.

### Document management

- Clearly define documents required based on event type.
- Use electronic file attachments.
- Leverage document redaction, annotation and translation tools.
- Compile an electronic dossier as a PDF chapter book with a table of contents packaged for adjudicators.

### Reporting and analytics

- Adjudication tracker
- Adjudication phase distribution
- Event type breakdown
- Event aging
- Adjudicator workload
- Missing source documents
- Billable events

### Data integration for stand-alone use

- Map and import data from any source using the data migrator tool.
- Custom programming is not required.
- Create and apply filters and formatters.
- Define recurring import frequency.

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## User experience

Using this solution, Baim Institute for Clinical Research significantly reduced its adjudication timeline.

“Number one, we needed an option that would let us tailor aspects of the workflow to our needs, and IBM Clinical Development fit that perfectly.”

“We’ve always had very good endpoint adjudication processes, but we were still performing many tasks manually. After implementing IBM Clinical Development Endpoint Adjudication, we’ve cut our timeline by an average of 30 percent.”

– Baim Institute for Clinical Research

## Additional features of Endpoint Adjudication Translation

### capabilities

- The system has an automated translation process for any uploaded source document.
- Adjudicators can perform assessments in the language of their choice.

### User-friendly interaction

- Configure every page of the endpoint adjudication workflow as any standard case report form page to handle document review, medical review and adjudication steps.

### Document review

- Mark up documents online — including redactions, highlights and text notes.

### Single dashboard

- Combine workflows and endpoint management in a single collaborative workspace.
- Manage every aspect of adjudication— from start to finish.
- Enable authorized users, such as Critical Events Committee (CEC) members, to access original study documents and essential workflows, including paired consensus, parallel review, expert review and direct communications.

### Automated checklists and notifications

- Monitor outstanding tasks related to event coordination workflow and team progress.
- Set up automatic alerts when documents are ready for review.

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# Support and services

## Training and design resources within IBM Clinical Development



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Services include:

- Training using the trainees’ studies
- Full-service study build and project management
- Training manuals and videos created for the user

IBM training covers the entire platform, including:

- EDC core
- Data integration
- Study build instruction
- Advanced expression editor
- Mid-study update
- Solution options
- Advanced expression editor
- Reporting and analytics
- Study testing
- Data management training
- End-user training
- Site training

### Study Build Services

#### Full-service

- Completed study design and build per client specifications
- Comprehensive project management to ensure accurate study budget and build timeline
- Software quality assurance validation
- Up to 5 studies (per client Specifications) package  
Option custom data import option

#### Build assistance

- One-on-one, hands-on Guidance to expedite build and study design
- Self-paced training (build yourself)

#### Custom SAS datasets

- Completed SAS datasets (SAS or CSV format) customized to Sponsor, CRO or client specifications
- Variable names and external System formatting needs (note: SDTM-formatted Datasets currently are not Within scope of service)

# Other capabilities

## Additional tools and features within IBM Clinical Development

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- Study designer**
  - Enable study designers to build, test and set studies live with minimal technical experience using an easy-to-use interface.
  - Build even the most complicated scenarios with point-and-click and drag-and-drop functions.
  - Import a full study design, workflow or various other aspects to get studies up and running in a fraction of the time.
  - Use the CDISC-CDASH form library, provided by IBM, to start a build or create template libraries.
- Study testing**
  - Provides a comprehensive list of testing scenarios based on the specific design of the study and enables the addition of ad hoc scenarios
  - Enables testers and study designers to add their findings throughout the testing process
  - Provides a comprehensive document, including all information captured during testing with full audit trail and traceability matrix
- Training tracking**
  - Helps ensure that users review training materials, watch an instructional video and pass an online assessment before gaining access to the study
  - Allows demonstration of FDA training compliance at research sites with a training certificate for each user that can be filed within the study documentation
  - Minimizes the need to hold multiple, live training sessions, schedule retraining, or keep up with individual training
- Site documents**
  - Enables users to upload documents directly within the platform at a site level
  - Collects information related to a specific site or subjects
- Lab normals**
  - Normalize laboratory values across associated local labs to account for differences in formats, content and test methods
  - Collect ranges and apply them to subject results for cleaning
  - Enable reviews with a filterable standard report



- DICOM imaging**
- Upload, store and view Digital Imaging and Communications in Medicine (DICOM) images directly into IBM Clinical Development.
  - Upload different types of images, such as MRI, CT or PET, to a subject time point, eliminating CDs and shipping costs.
  - View images with iConnect Access, a zero-footprint, lightweight image viewer.

- Monitoring levels**
- Take a targeted or reduced approach to monitoring activities.
  - Create user-defined “buckets” that can be as broad as locale or site, and as granular as the subject level.
  - Define source data verification as optional or required on a field-by-field basis.
  - Move regions, sites and subjects between buckets as monitoring activities dictate—all within IBM Clinical Development.

- Risk-based monitoring**
- Users can take a risk-based approach to monitoring sites and subjects.
  - In conjunction with monitoring levels and risk-based monitoring partnerships, data is interchanged and reviewed.
  - Feedback on status of source data verification is provided.
  - Modifications to source data verification plans for sites and subjects are provided by using advanced visualizations, analytics, and machine learning for risk prediction, detection, analysis and management.

- Monitor management**
- Track interactions and tasks at the responsible site during a phone, remote or site monitoring visit.
  - Follow a study-specific visit plan that can be designed using a template by the monitor manager.
  - Track and monitor activities during visits, facilitating the tracking of findings, corrective actions, resolutions and trip reports.
  - Review submitted site visits, and use a signature to approve or reject the visits.
  - Communicate with the monitor through the discussion tool in the system.

- Payments**
- Automated site payments with eClinicalGPS with end-to-end visibility into payment statuses
  - Optimized workflow efficiencies to gain financial transparency and navigate global payment execution

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**Language translation**

- IBM Clinical Development is translated into over 30 languages.
- Designer users can manage translations of their case report forms through simple download and upload of a csv file.
- Site users and subjects can access studies in their native languages based on their selection on the system login screen.

**Document translation**

- IBM Clinical Development integrates seamlessly with an industry-leading translation partner.
- Users benefit from automatic transfer of uploaded source documents to the translation provider and the automatic return of the translated document, saving time and reducing tracking errors.

**Study Connect mobile access**

- Gain quick access to study data, such as for charts, graphs, reports and key metrics, with this mobile application.
- Get customized alerts and notifications, such as when an adverse event occurs, a site is activated or a subject is enrolled.
- Handle randomization, dispensing and emergency unblinding on iOS-enabled devices, such as an iPhone or iPad.

**Safety reporting**

- Helps facilitate the exchange of data between IBM Clinical Development and safety platforms
- Allows users to generate safety reports based on defined parameters
- Creates a readable Individual Case Safety Report (ICSR), sends a PDF-formatted file by email, and uses the submission process to transfer XML data to a location outside of the system
- Delivers notifications and submissions, configured with various timing options, to meet needed workflows

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# Early phase clinical studies

## IBM solutions for the demands of early phase trials

- **EDC.** Launch trials quickly using a system that integrates with other solutions and provides quick access to essential data.
- **Medical coding.** Reduce delays in adverse event reporting with uniform, accurate coding.
- **Data integration.** Reduce hands-on time using automated data migration technology.
- **Reporting and analytics.** Guide study decisions using dynamic dashboards and clearly presented reports.
- **Randomization and trial supply management.** Help ensure patient safety through reliable randomization and dispense processes that are fully integrated with the EDC system.

IBM Clinical Development supports a variety of clinical study types and has two decades of experience in early phase trials that enroll a small group of patients. This experience contributes to the overall success of these trials.

IBM Clinical Development has helped over 200 companies with early phase studies and continues to find solutions for considerations users value most, such as:

|                            |   |
|----------------------------|---|
| <b>Data capture</b>        | Creating early phase study resources, from case report forms to digital dossiers, requires the ability of systems to capture data accurately and present it to users expediently. EDC and medical coding from IBM Clinical Development are among the solutions that provide such invaluable data management.  |
| <b>Rapid deployment</b>    | IBM Clinical Development can help reduce study launch times through adoption of its main software solutions, offered either as distinct services or a unified system. This ability is particularly valuable for early phase trials that influence the trajectory of study completion and time to market. Also, the drag-and-drop function helps build studies without the need for programming. |
| <b>Global and scalable</b> | This end-to-end platform is ideal for small early phase, mid-sized enterprise, and large global trials. You can gather, analyze and report data for any type, size, or therapeutic area. IBM Clinical Development has run trials in over 80 countries and available in 30+ languages.   |

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## Why IBM Watson Health?

IBM solutions—from data capture to endpoint adjudication—are the groundwork for new ventures and directions.

It's not just about IBM's strengths in clinical study design and management. It's about exploring blockchain technology with the FDA. It's about hosting one of the most security-rich computing clouds in the world. It's about IBM's patient-centric approach.

With IBM Watson technology, patient engagement is expected to improve dramatically over time, especially with the latest trends in wearable devices and sensors. Watson can retrieve volumes of data from many medical sources, including electronic health records and insurance claims data.

It can also work to help protect patient privacy, allowing clinical, research and social health information to be aggregated, analyzed and shared in a security-rich IBM cloud that complies with government regulations and industry standards.

Combined with the cognitive computing ability of Watson to rapidly derive meaning from voluminous networks of data, there are technological solutions and enhancements underway at IBM to help enrich patient care.

### For more information

To learn more about IBM Clinical Development from Watson Health, please contact your IBM representative or IBM Business Partner, or visit: [ibm.com/watson/health/life-sciences](http://ibm.com/watson/health/life-sciences).

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