
CLIPS®
Clinical Pharmaceutical
Smart Support Solutions

# WHO ARE WE?

CLIPS
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We are a Colombian private outsorcing company; Leader and Pioneer in providing integral support services for health and pharma industry as:

- Pharmaceutical Industry.
- Clinical Research Organizations (CROs).
- Insurance companies.
- Medical devices and Biotechnological Companies.
- Healthcare providers.

# OUR SERVICES

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- **Source Documentation creation for Clinical Data Collection and Quality control**
- **Clinical Data Processing (Data Entry) and quality control**
- **Call Center patient recruitment, monitoring and patient study adherence**
- **Sells for healthcare and pharma industry**
- **Telehealth: Patient Support and specialized medical assistance and follow up.**
- **Back-office Services: Medical Billing management, accountability, scanning, patient medical record data entry.**
- **Qualified Staff Support/Solution for Clinical Research**

# SOURCE DOCUMENT CREATION

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We offer solutions for health companies in need of high quality and standardized/ individualized source documents for collecting the clinical data by creating them with all the clinical information to fulfill the needs of each trial/protocol and sponsor contracts.

Our methodological process to build source documentation guarantee an accurate study data collection, according to the protocol requirements through a consistent quality control process.

# QUALITY CONTROL

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Quality control for clinical trial documents is an essential service that ensures the integrity, accuracy, and compliance of all documentation throughout the trial process. This service involves meticulous review and verification of documents such as clinical protocols, informed consent forms, case report forms, and regulatory submissions, ensuring they meet regulatory requirements and industry standards.


The quality control process helps identify and correct any discrepancies or errors, mitigating the risk of non-compliance or data inconsistencies. It also facilitates the smooth progression of the trial, promoting transparency, reliability, and trustworthiness of the study's results. Ultimately, quality control services are crucial in maintaining the credibility of clinical trials and safeguarding participant safety

# QUALITY CONTROL

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With an accurate training process our Team will be capable of:

**1.Document Review and Verification**: QC staff are responsible for thoroughly reviewing clinical trial documents, such as protocols, case report forms (CRFs), informed consent forms, and regulatory submissions. They verify that all documents are complete, accurate, and compliant with regulatory standards (e.g., FDA, EMA) and industry guidelines (e.g., ICH-GCP).

**2.Ensuring Compliance**: They ensure that all trial documents comply with relevant laws, regulations, and ethical standards. This includes confirming that informed consent forms are clear, comprehensive, and properly executed and that all documents meet Good Clinical Practice (GCP) and Good Documentation Practices (GDP) guidelines.

**3.Error Detection and Correction**: QC personnel meticulously identify and resolve discrepancies, typographical errors, or inconsistencies within trial documents. They work to correct any mistakes before the documents are submitted to regulatory authorities or used in clinical operations.

# QUALITY CONTROL

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**4. Tracking and Auditing**: They maintain detailed records of document revisions, approvals, and changes. QC staff may also conduct periodic audits of trial documentation to ensure ongoing adherence to quality standards and procedures.

**5. Collaboration with Other Departments**: QC teams work closely with clinical operations, regulatory affairs, data management, and other departments to ensure that the trial documents are aligned with study protocols and objectives. They provide feedback and guidance to team members on quality standards and best practices.

**6. Training and Development**: Well-trained QC staff may also be involved in training other team members on quality control procedures, document handling, and regulatory requirements to maintain high standards across the organization.

**7. Reporting and Documentation**: They are responsible for generating QC reports that document their findings, corrective actions, and recommendations. These reports are essential for internal tracking and for submission during regulatory inspections or audits.

**8.** E**nsuring Data Integrity**: In addition to documentation, QC staff may be involved in verifying the integrity of clinical data collected during the trial to ensure that it is accurate, complete, and consistent with trial protocols.

# Clinical Data Processing (DATA ENTRY)

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A well-trained staff in the Data Entry department is essential for ensuring that clinical trial data is accurately and efficiently recorded, stored, and managed. Their key job functions include:

**1. Data Entry and Transcription**: The primary responsibility of data entry staff is to accurately input clinical trial data into electronic databases or case report forms (CRFs). This includes transcribing patient information, medical histories, treatment regimens, test results, adverse events, and other relevant clinical trial data.

**2. Data Verification and Validation**: Data entry staff must carefully cross-check the entered data for accuracy, consistency, and completeness. This includes validating data against source documents (e.g., clinical notes, laboratory results) to ensure there are no discrepancies or errors. They are also responsible for flagging any inconsistencies or outliers for further investigation.

# Clinical Data Processing (DATA ENTRY)

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**3. Adherence to Protocol and Guidelines**: Data entry staff must ensure that data entry is conducted in strict adherence to the study protocol,regulatory requirements (such as GCP standards), and internal procedures. They follow Good Clinical Practice (GCP) and Good Documentation Practice (GDP) guidelines to ensure data quality and integrity.

**4. Handling Data from Multiple Sources**: Clinical trial data is often collected from various sources, such as patient visits, laboratory reports, clinical notes, and imaging results. Data entry staff must be able to manage and accurately input data from diverse formats and systems, ensuring proper organization and integration within the study's database.

**5. Data Coding**: In some cases, data entry staff may be responsible for coding medical terms (e.g., adverse events, diagnoses) using standardized coding systems such as MedDRA or WHO Drug Dictionaries. Accurate coding is crucial for data analysis and regulatory submission.

# Clinical Data Processing (DATA ENTRY)

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**6. Data Query Resolution**: ataD entry staff are responsible for resolving data queries that arise during the data cleaning process. This may involve reviewing source documents, consulting with clinical staff, or communicating with other departments (e.g., clinical operations, monitoring) to clarify discrepancies or missing data.

**7. Maintaining Data Confidentiality**: Given the sensitive nature of clinical trial data, data entry staff must ensure the confidentiality and security of all patient information. This includes following strict privacy protocols and data protection regulations, such as HIPAA or GDPR.

**8.Generating Reports**: Data entry staff may be tasked with generating reports that track data entry progress, identify potential data discrepancies, and highlight any issues that need attention. These reports assist in monitoring the overall quality of the data being entered.

# Clinical Data Processing (DATA ENTRY)

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**9.Collaboration with Other Teams**: Data entry personnel are able to collaborate closely with other departments, such as clinical operations, data management, and quality control, to ensure smooth data collection and entry processes. They may communicate with clinical research associates (CRAs) to resolve data discrepancies or clarify protocol requirements.

**10. System and Database Management**: Data entry staff will be proficient in using electronic data capture (EDC) systems, clinical trial management systems (CTMS), and other data management tools. They ensure that data is entered into the correct fields and stored in a way that supports efficient data retrieval and analysis.

By performing these functions, data entry staff will ensure that clinical trial data is accurately captured, organized, and available for analysis, which is crucial for maintaining the integrity of the study and ensuring reliable and valid results.

# Telehealth

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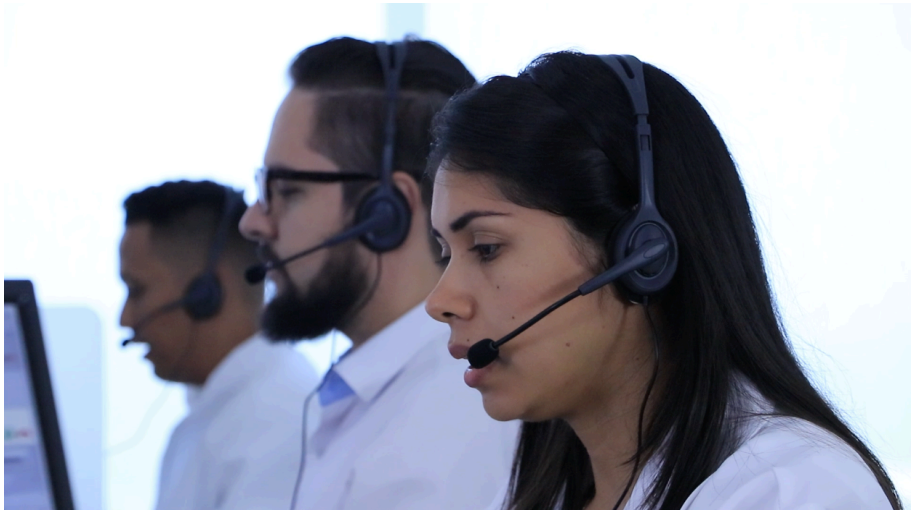
Our Telehealth services use digital communication tools and technologies to facilitate remote patient monitoring, consultation, data collection, and care delivery. These services aim to improve patient access, enhance trial efficiency, and ensure the safety and compliance of participants. Key aspects of telehealth services for clinical trials include:

1. **Virtual Consultations and Check-ins**
   a. Enable participants to connect with trial investigators, clinicians, or coordinators through secure video conferencing or telecommunication platforms.
   1. Allow for real-time assessment of patient health, adverse events, and protocol compliance without the need for in-person visits.
2. **Remote Patient Monitoring (RPM)**
   1. Use wearable devices, mobile apps, or other health-monitoring technologies to collect vital signs, activity levels, and other relevant metrics.
   2. Facilitate real-time tracking and automated alerts for deviations in patient health or adherence to the study protocol.



# Patient Reported Outcome

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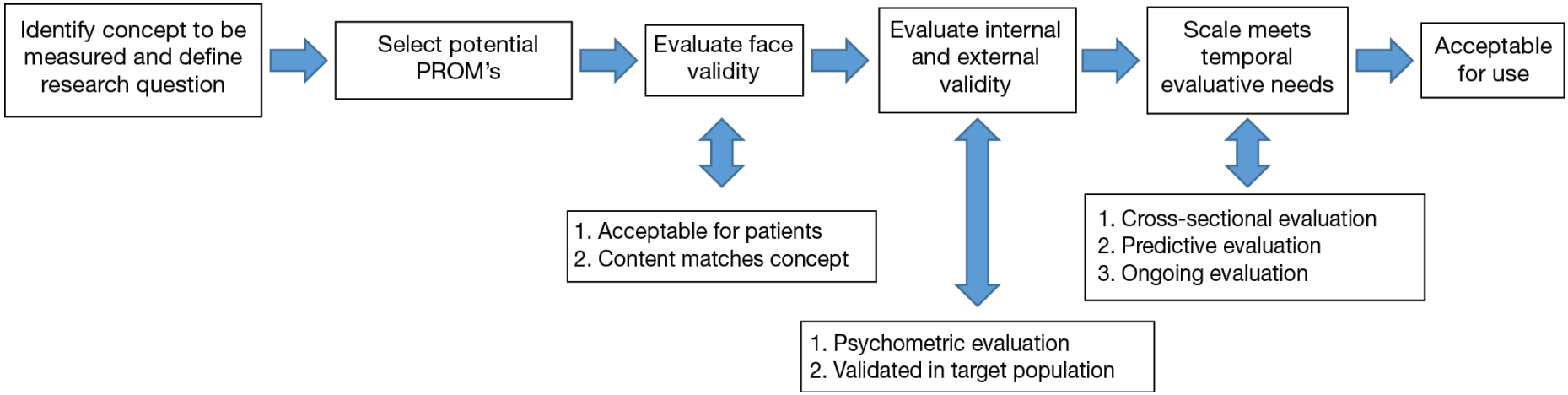


For our company, Patient Reported Outcome (PRO) service is an invaluable resource that accompanies our ultimate goal, the patient's welfare. Lately, it has been an increased focus on giving the patient a center stage on health care research.

We perform this service through two main channels, 1) Telehealth platform with specialized and trained health professionals; 2) On line Health Validated Questionnaire.

# Back Office Services

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EFG solutions provides services for hospitals, health care providers, insurance companies  and medical private practice that requires a back-office management. We can improve your medical-finances and organizational-environment by maximizing reimbursements and reducing your costs.


What can we do for you?
Our solutions includes, but are not limited to:

- Medical Billing Management
- Accountability
- Scanning
- Patient information and medical record Data Entry

**Let us help you ensure a cost-effective organizational environment.**

# Qualified Staff support / solution

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We hire the best qualified professionals with bilingual knowledge and provide training in the required ares. We work close with

# Why should you prefere us?

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- Our internet comunication channels between our costumers, providers and clients are blocked through SSL SHA-256-bit with RSA 2048 algorithm.
- Network supervised 24x7 againts any potential threat (data vulnerability, adware, hackers, pop-ups and possible pishing).
- In Colombia we are governed by Law 1581 of 2012 and Decree 1377 of 2013 for the protection of personal data. In addition, as flexible as we can be, we adapt for international rules for the security of medical information, such as HIPAA
- Daily Back-up for safety in a cloud-based server avoiding data lost or corruption, managed by a profesional IT manager.
- Since the begining, we signed confidentiality agreements between our clients and the company.
- Our employees have an average age of 25 years
- Lower work absenteeism, meaning more commitment
- Permanent employees and temporary employees, flexibility of increase or decrease according to their needs
- 48.5% increase in adherence of patients to clinical trials, meaning we have efficient strategic multichannel solutions
- We have a team of experts in sanitary consultancy for import and export of medicines, medical equipment and medical or biomedical devices according to the requirements of INVIMA
- The building has total power supply for 8 continuous hours, meaning uninterrupted work.

# WHY BARRANQUILLA?

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- Barranquilla is the second state in Colombia with the highest foreign direct investment (2016)
- In the 2010-2017 period, Barranquilla received USD $3,5 Billions in Direct Investment, contributing with the 4,3% of the national GDP (Gross Domestic Product)
- Barranquilla is the 2nd Largest South American State of the future 2016/2017 according to Financial Times.
- Is the 2nd city with lowest unemployment rate in Colombia during 2017, 8,2%
- Located in a low risk zone for hurricanes and earthquakes
- Most diversified economy in the country
- Atlántico is the port of entrance of 4 of the 10 submarine cables, allowing 3 Multinationals owners to distribute a Fiber Optic Network with lower costs, high redundancy and fast data transportation.
- Connectivity by air: Barranquila has the 2nd Airport with more passenger movement in the Caribbean Region. 2.632.053 passengers in 2017
- 1 hour flight from Bogotá's airport with 920 international frequencies and 6.125 national frequencies per week.
- Barranquilla is an important platform for trade thanks to its strategic location in the Caribbean, which allows you to be just 2 hours from the United States and one hour from Panama by air. It is located in the center of the port region of the Colombian Caribbean, less than 60 miles from the ports of Cartagena and Santa Marta.
- Barranquilla has a port infrastructure comprising more than 20 port concessions and a dozen terminals in one, which allows transport of all types of cargo to the rest of the country and the world.


Griselda Bermudez.
CEO and Founder
Address: Kra 53 # 80-198
Phone Number: +57 3004782645
E-mail: griseb@me.com