

Introducing TrialManage.AI

Streamline Retrospective Clinical Trials
platform/ Quicker & Smoother execution
of Real-World Evidence studies

Features

For Pharma Teams:

- **Centralized Dashboard:** Access a comprehensive dashboard for all trials.
- **Role-Based Access:** Provide role-based access to managers.
- **Real-Time Information:** Obtain detailed, real-time information on doctors and CRFs.

For CRO Teams:

- **Centralized Trial Management:** Manage multiple clinical trials simultaneously across different pharmaceutical companies.
- **Contract Management:** Add and manage contracts efficiently.
- **Batch Onboarding:** Onboard doctors in batches using CSV uploads.
- **Search and Communication:** Utilize search functionality to identify doctors and send onboarding emails.

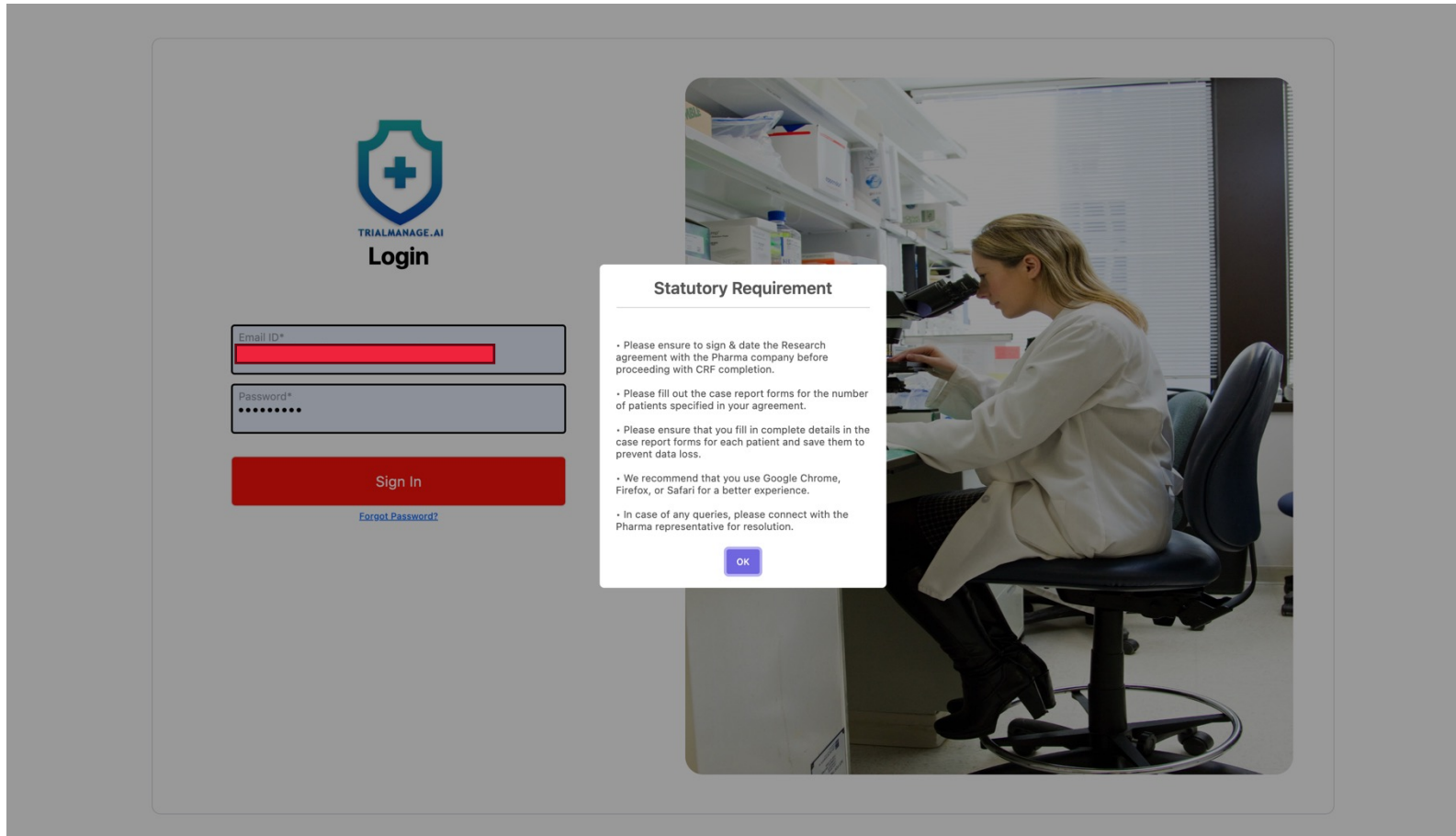
For Doctors:

- **Single-Time Detail Upload:** Upload personal details (PAN, Bank Account details, GST certificate) once, with the system storing them permanently.
- **Responsive CRF Forms:** Fill out CRF forms on mobile, tablet, or laptop/desktop devices.

Onboarding Efficiency:

- **Quick Onboarding:** Onboard a Pharma team and their studies in less than 24 hours

Login Page



- This serves as the login page for all users of the application.
- Upon logging in, users will encounter a list of guidance instructions.
- Acceptance of this list will determine redirection to the appropriate landing page corresponding to their associated role.



Pharma Admin

- **Clinical Trial Management**

Pharma administrators oversee multiple clinical trials, ensuring compliance with regulatory requirements in addition to managing budgets.

- **Role-Based Access Control**

Pharma administrators can provide role-based access to Project Managers for specific trials, allowing them to manage only their assigned trials while the admin maintains visibility over all trials.

Pharma Landing Page

Protocol ID	Total No. Of Doctors	Registered Doctors	Unregistered Doctors
IND/ACL/01	427	<u>234</u>	<u>193</u>
IND/ANM/01	985	<u>529</u>	<u>456</u>
IND/CLBP/01	521	<u>181</u>	<u>340</u>
IND/DM/01	134	<u>121</u>	<u>13</u>
IND/HMC/01	662	<u>336</u>	<u>326</u>
IND/MEL/01	69	<u>56</u>	<u>13</u>
IND/OP/01	288	<u>170</u>	<u>118</u>
IND/PCOS/01	269	<u>145</u>	<u>124</u>

- Upon logging in, the admin from the Pharma Team is presented with a landing page displaying all ongoing trials associated with a specific pharmaceutical company.
- This page provides essential details such as Protocol ID and the number of doctors who are registered or not registered for each trial.
- Further information can be accessed by clicking on the numbers indicating the registered or unregistered doctors.
- Note: The Pharma Project Manager will have access to the same screens as the admin but can see information only for their assigned trial(s).

Registered Doctors (Per Trial)

Protocol Id: IND/ACL/01
Global Search...

Welcome! Ashwath Alva Log Out

Doctor Name	Doctor Email	CRF Uploaded
PRASANTA KUMAR MOHANTY	[REDACTED]	Total CRF: 0 Submitted CRF: 0 Not Submitted CRF: 0 Export patient data
SACHIN KIRAN PATIL	[REDACTED]	Total CRF: 5 Submitted CRF: 5 Not Submitted CRF: 0 Export patient data
Aakanksha Rade	[REDACTED]	Total CRF: 0 Submitted CRF: 0 Not Submitted CRF: 0 Export patient data
ARUN GOPIKISHAN BAGDIA	[REDACTED]	Total CRF: 0 Submitted CRF: 0 Not Submitted CRF: 0 Export patient data
ABDHUT PRADHAN	[REDACTED]	Total CRF: 0 Submitted CRF: 0 Not Submitted CRF: 0 Export patient data
SRIHARI KANTHILA	[REDACTED]	Total CRF: 2 Submitted CRF: 2 Not Submitted CRF: 0 Export patient data

© 2024, CLIRES.AI

- On this page, you'll find a paginated roster of registered doctors.
- You can conduct searches based on the doctor's name and/or email address.
- By clicking "Export patient data," you can access a PDF summary of the CRFs.
- To review completed CRFs, simply click on the email address, which will redirect you to a page displaying patient and CRF details.

Patient and CRF information

The screenshot displays the TRIALMANAGE.AI Reports interface. On the left is a blue sidebar with a white shield logo containing a cross and the text 'TRIALMANAGE.AI' and 'Reports'. The main content area shows a 'Welcome! Ashwath Alva' message with a 'Log Out' button. Below this, a table lists CRFs with columns for 'CRF Patient ID' and 'Submitted Date'. The table contains five rows of submitted CRFs. Below the table, a detailed view of a CRF form is shown for Patient ID: 01. The form includes fields for Protocol Number, Sponsor, Patient No, Patient Initials, Date of Enrollment, and Patient Identification (Age, In Years, Gender).

CRF Patient ID	Submitted Date
01 (Submitted)	May 9, 2024, 5:25:09 PM
02 (Submitted)	May 9, 2024, 5:25:09 PM
03 (Submitted)	May 9, 2024, 5:25:09 PM
04 (Submitted)	May 9, 2024, 5:25:09 PM
275867 (Submitted)	May 9, 2024, 12:23:58 PM

CRF Details:

Protocol Id : IND/ACL/01
Doctor Name : SACHIN KIRAN PATIL
Doctor Email : [REDACTED]

Patient Id : 01

CASE REPORT FORM
Exploring Amoxicillin and Clavulanic Acid Prescribing Practices: A Retrospective Analysis

Protocol:
Protocol Number: IND/ACL/01

Sponsor:
Indchemie Health Specialities Pvt. Ltd

PatientNo:
01

Patient Initials:
k M

Date of Enrollment:
07/01/2024

Patient Identification:
Age: 54
In Years: [REDACTED]
Gender: Male

- This page displays a paginated list of CRFs, each accompanied by a timestamp indicating when it was completed.
- Clicking on any patient ID allows you to view the CRF form in read-only mode, enabling you to review the submitted details.

Unregistered Doctors (per trial)

The screenshot displays the TRIALMANAGE.AI interface. On the left is a blue sidebar with a white shield logo containing a cross, the text 'TRIALMANAGE.AI', and a 'Reports' button. The main content area shows a 'Welcome! Ashwath Alva' message with a 'Log Out' button. Below this is a 'Protocol Id: IND/ACL/01' and a 'Global Search...' input field. The central part of the page features a table with two columns: 'Doctor Name' and 'Doctor Email'. The table lists 16 doctors, with their email addresses redacted. A 'Load More' button is located at the bottom of the table. The footer of the page contains the copyright notice '© 2024, CLIRES.AI'.

Doctor Name	Doctor Email
ARBAAZ ASHFAK SAYYED	[REDACTED]
ABHAY SAHEBRAO MHASKE	[REDACTED]
ABHIMANYU SAHU	[REDACTED]
ADITYA NARAYAN SAHU	[REDACTED]
CHAITANYA M N	[REDACTED]
ABDUL JALEEL	[REDACTED]
Dr AKASH	[REDACTED]
SANJAY TULJARAM AKOLKAR	[REDACTED]
AMAR A RASAL	[REDACTED]
AMITKUMAR K ARORA	[REDACTED]
BOTHARA AMIT RIKHABCHAND	[REDACTED]
SRIKANT YALWANTAGI	[REDACTED]
ANAND SHEDBAL	[REDACTED]
ANIRUDDH DASH	[REDACTED]
AFROZ PASHA	[REDACTED]

- This page will present the names and email details of unregistered doctors.
- Similar to the Registered Doctors page, you can utilize the search function to look up doctors by name and email ID.

Doctor



- **Role in Clinical Trials**

Doctors play a critical role in clinical trials, from patient recruitment to data collection. They help ensure that clinical trials are safe and effective for patients.

- **Doctor Registration and Role**

After completing the registration process, doctors are able to access their accounts and input various information such as their PAN card, Banking details, and GST certificate. Subsequently, they can review the trials they've been designated to participate in and upload patient CRF forms to the platform upon agreeing to the Terms and Conditions.

Doctor Landing Page



Welcome! **Dr. Sunil Chaudhary**



Log Out

Protocol ID: IND/ACL/01

Title: Exploring Amoxicillin and Clavulanic Acid Prescribing Practices: A Retrospective Analysis

Agreement ↓

Protocol PDF ↓

Protocol ID: IND/ANM/01

Title: Understanding Approaches in Managing Anemia in Women: A Retrospective Questionnaire-Based Study

Agreement ↓

Protocol PDF ↓

- After being onboarded, doctors receive an email containing a link to access the application along with their credentials.
- Upon logging in, they are directed to the landing page, displaying all the studies they have access to.
- Clicking on the "Agreement" button for a specific study will initiate the download of the Study Agreement, and likewise, clicking on the Protocol PDF button will download the Protocol document.
- Clicking on the study will take them to the study specific pages

Study Agreement Page

View Study : IND/ACL/01

Welcome! **Dr. Sunil Chaudhary** Log Out

Study Agreement

Upload Signed Study Agreement :

Drag & Drop or Browse Files (Upload in JPG, PNG or PDF format. Max size allowed 5 MB per upload)

View Uploaded Study Agreement

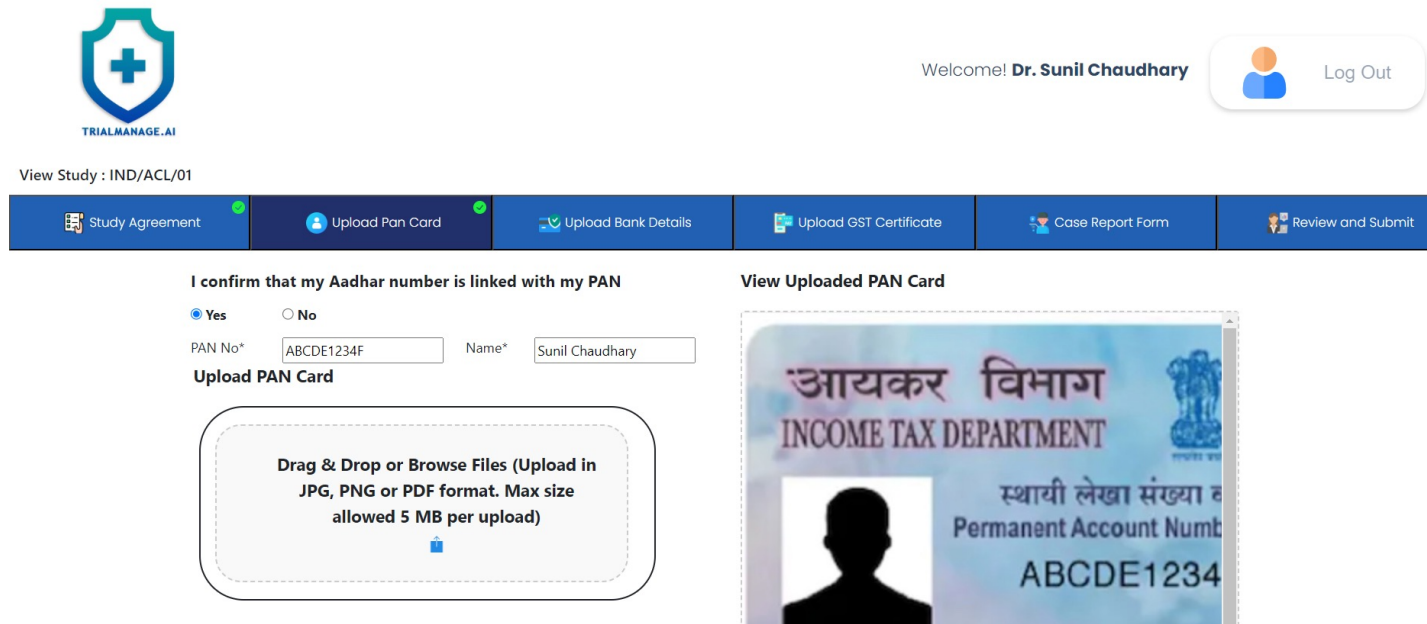
Clinical Research Protocol

Study Title: Exploring Amoxicillin and Clavulanic Acid Prescribing Practices: A Retrospective Analysis

Study Code: IND/ACL/01
Protocol Version: 1.0
Date: 15-Apr-2024

- On this page, the doctor can upload the signed study agreement

PAN Card Upload Page



The screenshot shows the PAN Card Upload Page interface. At the top left is the TRIALMANAGE.AI logo. The user is logged in as Dr. Sunil Chaudhary, with a 'Log Out' button. A navigation bar contains: Study Agreement, Upload Pan Card (active), Upload Bank Details, Upload GST Certificate, Case Report Form, and Review and Submit. The main content area has two sections: 'I confirm that my Aadhar number is linked with my PAN' with 'Yes' selected, and 'View Uploaded PAN Card' showing a sample PAN card with details: PAN No* ABCDE1234F, Name* Sunil Chaudhary, and Permanent Account Number ABCDE1234. An upload area prompts the user to drag & drop or browse files (JPG, PNG or PDF format, max size 5 MB per upload).

- On this page, the doctor can upload the PAN card photo as well as provide the details.
- This is a one-time activity and for all subsequent studies where the doctor is involved, the system will show the existing details.

Bank Details Upload Page

View Study : IND/ACL/01

Study Agreement | Upload Pan Card | Upload Bank Details | Upload GST Certificate | Case Report Form | Review and Submit

Bank Account No* 66666666666 Name* Sunil Chaudhary

Bank Account Type* Savings IFSC Code* BHDG0298333

Upload a cancelled cheque

Drag & Drop or Browse Files (Upload in JPG, PNG or PDF format. Max size allowed 5 MB per upload)

View Uploaded Cheque

- On this page the doctor can provide his bank account details and upload a cancelled cheque as well.
- This is a one-time activity and for all subsequent studies where the doctor is involved, the system will show the existing details.

GST Certificate Upload Page

The screenshot shows a web application interface for uploading a GST certificate. At the top left is the TRIALMANAGE.AI logo, a blue shield with a white cross. To the right, a user is logged in as Dr. Sunil Chaudhary, with a 'Log Out' button. Below this is a progress bar with six steps: 'Study Agreement', 'Upload Pan Card', 'Upload Bank Details', 'Upload GST Certificate' (the current step, highlighted in dark blue), 'Case Report Form', and 'Review and Submit'. The main content area is divided into two sections. The left section, titled 'Are you liable to pay GST?', includes instructions to upload the certificate if 'Yes' and a 'Next' button if 'No'. The 'No' radio button is selected. Below this is a file upload area with a dashed border and a blue folder icon, containing the text: 'Drag & Drop or Browse Files (Upload in JPG, PNG or PDF format. Max size allowed 5 MB per upload)'. The right section, titled 'View Uploaded GST Certificate', contains a large, empty dashed rectangular box. At the bottom center of the right section is a blue 'Next' button.

- At this point, the doctor can provide his/her GST certificate if they are liable to pay GST.
- If not, they can select NO and move on to the next step.

Manage Case Report Form Page

The screenshot shows a web application interface for managing case report forms. At the top left is the TRIALMANAGE.AI logo. The top right displays a welcome message for Dr. Sunil Chaudhary and a Log Out button. A horizontal navigation bar contains six steps: Study Agreement, Upload Pan Card, Upload Bank Details, Upload GST Certificate, Case Report Form (highlighted with a green dot), and Review and Submit. Below the navigation bar, the study title 'IND/ACL/01' and subtitle 'Exploring Amoxicillin and Clavulanic Acid Prescribing Practices: A Retrospective Analysis' are shown. The main section is titled 'Patient/Survey Data Input' and contains a 'List of Patient IDs' box with two entries: '13 (CRFs completed)' and '15 (CRFs completed)'. Below this box are buttons for '+ Add Patient' and 'Download Patient Summary'. A 'Next' button is located at the bottom right of the main content area.

- At this point, the doctor can begin completing CRFs and updating any existing ones.
- Additionally, they can opt to download a PDF summary of the CRFs.
- By clicking on "Add Patient" or selecting any existing CRF from the List of Patient IDs box, they will be directed to the CRF page.

Case Report Form Page

←

Patient Id

CASE REPORT FORM
Exploring Amoxicillin and Clavulanic Acid Prescribing Practices: A Retrospective Analysis


Protocol:

Protocol Number
IND/ACL/01

Sponsor
Indchemie Health Specialities Pvt. Ltd

PatientNo

Patient Initials

Date of Enrollment 
dd/MM/yyyy

Patient Identification:

Age

In Years

Gender

Male / Female / Other

Medical History

Primary reasons for Amoxicillin + Clavulanic acid Rx

Prescription Details

Amoxicillin/Clavulanic Acid Dosage

Dosage of amoxicillin and clavulanic acid prescribed

Duration of Treatment

Duration of treatment with amoxicillin and clavulanic acid in days


Frequency of Prescription

Prescribed frequency for amoxicillin and clavulanic acid

Reason For Choosing Treatment

The primary reason to choose amoxicillin and clavulanic acid over other antibiotics

Did you prescribe any other medication concurrently with Amoxicillin and Clavulanic Acid?

Date of Follow up visit 
dd/MM/yyyy

Your Rating for the Treatment

How would you rate the response to treatment with Amoxicillin and Clavulanic Acid?

Adverse Drug reaction

Check all that apply

Did you experience any other adverse effects or complications associated with Amoxicillin and Clavulanic Acid?

Prescribing Trends

Adjuvant Therapies

Other medications prescribed alongside amoxicillin and clavulanic acid

Healthcare Setting

Healthcare Setting

Hospital / Clinic

- EDC page is designed based on the EC approved CRF template.
- It features a digital form incorporating dropdown menus, radio buttons, and multiple-choice responses to make filling process easy & quick.
- The form automatically saves progress every few seconds, allowing doctors to fill it out gradually over time per their convenience.
- Upon completion, the doctor can simply click the "Submit" button, and the form will be submitted.

Review and Submit page

TRIALMANAGE.AI

new Study : IND/ACL/01

Welcome! **Dr. Sunil Chaudhary** Log Out

Study Agreement | Upload Pan Card | Upload Bank Details | Upload GST Certificate | Case Report Form | **Review and Submit**

Dear Team

I have uploaded patient data. Patient data summary and statutory documents in originals are retained with me and will be made available as and when requested.

Regards,
Dr. Sunil Chaudhary

- After completing all the CRFs, the doctor can proceed to the next step to review and submit their work. Once submitted, the CRFs will be accessible to the Pharma team for validation and further processing.



Conclusion

TrialManage.AI is a versatile platform that helps accelerate the development of life-saving treatments by streamlining the trial process, improving data quality, and reducing administrative burden for clinical trial stakeholders.