

Instructions for Medinexo Clinical Sites on Data Retrieval for Participation in the Therapeutic Data Network

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Introduction

This document outlines the steps for clinical sites partnering with Medinexo to retrieve, format, and securely transfer patient data. The data collected will help clinical trial sponsors evaluate patient populations for potential inclusion in clinical trials and other research studies.

Providing this data is essential in determining whether your patient population meets the eligibility criteria for upcoming studies. By following these instructions, your site can participate in important research initiatives while adhering to data privacy and security standards.

Scope of Data Collection

You will need to extract specific tables from your patient database that focus on:

- Demographic data (e.g. date of birth, gender, race, ethnicity)
- Medical encounters (e.g. visit date, visit type)
- Conditions (e.g. ICD9 or ICD10 codes)
- Procedures (e.g. CPT or HCPCS codes or surgery names)
- Treatments and Medications (e.g. drug name, dosage, formulation, NDC code)

This data will be used by clinical trial sponsors to understand patient populations in order to assess eligibility for current and future research studies.

Data Transfer Guidelines

Data Extraction

Clinical sites must extract the relevant data from their databases and export it in **CSV (Comma-Separated Values)** format. CSV files offer a standardized and structured way to share large datasets, ensuring compatibility across different systems.

Data Upload Process

Once the CSV files are prepared, they must be uploaded to the **secure cloud storage environment** managed by Medinexo. Medinexo's cloud storage complies with data protection regulations to ensure patient data is securely handled.

< Medinexo to define data transfer >

Please inquire with suport@rhinohealth.com if you require assistance in this area.

Data Privacy and Security Requirements

While certain patient identifiers are necessary, personally identifiable information (PII) must be excluded as per GDPR and HIPAA regulations. **Do not include:**

- Patient names
- Addresses
- Phone numbers,
- Email addresses,
- National or state identity

- Passport number,
- Medical record numbers
- Genetic sequencing information

Technical Assistance with Data De-identification

In the case that your site lacks the means to ensure de-identified data, our technology partners at Rhino Health can either assist. Please inquire with suport@rhinohealth.com in the case that you are interested in receiving assistance in regards to the process and certification of data de-identification.

Specific Data Requirements

The following information must be included in each of the five tables that you provide Medinexo. **However, you simply provide de-identified copies of your local database, rather than renaming columns.**

1. Person Table (or equivalent) **Required**

- **Unique Patient Identifier:** A unique identifier for each patient, used consistently across all tables(e.g. 28395 or a3892nf389). No Personally-Identifying Information (PII) should be used for this field.
- **Year of Birth:** Record only the year, not the full date of birth.
- **Gender:** Record the patient's gender.
- **Race:** Record the patient's race using standard race classifications.
- **Ethnicity:** Record relevant ethnicity information for your region to ensure diversity of research participants. (Hispanic vs. Non-Hispanic, Indigenous vs. Non-Indigenous)

2. Conditions Table (or equivalent) **Required**

- **Unique Patient Identifier:** A unique identifier for each patient, used consistently across all tables(e.g. 28395 or a3892nf389). No Personally-Identifying Information (PII) should be used for this field.

- **Visit ID:** A unique identifier linking conditions to the patient encounter.
- **Dates:** Record the date of diagnosis or when the condition was identified.
- **ICD-9 or ICD-10 Codes:** Include the appropriate diagnostic codes from the International Classification of Diseases (ICD-9 or ICD-10). Codes should include characters after the decimal point.
 - Ex. ICD10 J05.0

3. Treatments Table (or equivalent) **Optional**

- **Unique Patient Identifier:** A unique identifier for each patient, used consistently across all tables(e.g. 28395 or a3892nf389). No Personally-Identifying Information (PII) should be used for this field.
- **Visit ID:** A unique identifier linking drug exposures to the patient encounter.
- **Dates:** Record the date the drug was prescribed or administered.
- **Drug Name:** Record the full name of the drug.
- **Drug Code:** Include the appropriate drug identification code (e.g., NDC, RxNorm).
- **Drug Dosage:** Record the dosage information for each drug.

4. Visits Table (or equivalent) **Optional**

- **Unique Patient Identifier:** A unique identifier for each patient, used consistently across all tables(e.g. 28395 or a3892nf389). No Personally-Identifying Information (PII) should be used for this field.
- **Visit ID:** A unique identifier for each visit to associate conditions, procedures, and drug data with the specific encounter.
- **Date of Service:** Record the date on which the patient received care.
- **Type of Service:** Specify the type of service provided (e.g., inpatient, outpatient, emergency).
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5. Procedures Table (or equivalent) **Optional**

- **Unique Patient Identifier:** A unique identifier for each patient, used consistently across all tables(e.g. 28395 or a3892nf389). No Personally-Identifying Information (PII) should be used for this field.

- **Visit ID:** A unique identifier linking procedures to the patient encounter.
- **Dates:** Record the date on which each procedure was performed.
- **Procedure Description:** Provide a brief description of the procedure.
- **Procedure Code:** Include the code associated with the procedure (e.g., CPT, HCPCS, or ICD procedure codes).

6. Laboratory Results Table (or equivalent) **Optional**

- **Unique Patient Identifier:** A unique identifier for each patient, used consistently across all tables(e.g. 28395 or a3892nf389). No Personally-Identifying Information (PII) should be used for this field.
 - **Visit ID:** A unique identifier linking procedures to the patient encounter.
 - **Dates:** Record the date on which each procedure was performed.
 - **Test Name:** Description of laboratory test.
 - **Test Units:** Units (e.g. mg/dL) of the test.
 - **Test Result:** Numeric value.
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File Format and Structure:

- All files must be submitted in XLSX or CSV format (**CSV preferred**).
 - Submit each table (Person, Visits, Conditions, Procedures, Drug Exposure) as a **separate file**.
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Next Steps

1. **Identify** the tables and fields in your database that contain the required data.
2. **Write** and execute a query to extract the data as CSV files.
3. **Upload** the CSV files to the secure Medinexo cloud environment, following the instructions provided.
4. **Verify** that no personally identifiable information (PII) is included, except for required fields like date of birth and gender.

If you have any questions or require further assistance, please contact support@rhinohealth.com.

Thank you for your cooperation in this important data collection effort. Your participation will help advance clinical research and contribute to the development of new treatments and therapies.