



Life Sciences Rules and Restrictions

Disclaimer:

- The following information is provided for general education purposes only and does not replace each customer's own training materials.
- The information presented is not legal advice. For specific rules and restrictions, each customer should review the applicable sections of the contracts in effect with Explorys.
- Each customer is responsible for the acts and omissions of its Authorized Users.

Key Terms:

Explorys Universe:

The aggregated, de-identified information that Explorys assembles from its healthcare provider subscribers' data which has been statistically de-identified to meet the requirements of 45 CFR § 164.514(b). This is the “expert determination” method.

Therapeutic Dataset:

A therapeutic cohort based on statistically de-identified information that is defined by inclusion criteria, and that may not be composed of the entire Explorys Universe of data.

Key Terms:

Raw Data:

Any atomic data element coming directly from a patient or provider in a therapeutic cohort created from a portion of Explorys Data, including raw procedure codes, resulting values (e.g., blood pressure, BMI), lab test results, diagnosis codes, birth dates, death dates, and record dates.

Summary Statistics:

Any aggregation, counting, or results of mathematical or statistical operations on data found within a Therapeutic Dataset that do not retain any Raw Data or any link back to specific Raw Data.

Why the rules and restrictions?

- Maintaining the statistical certification that applies to the Explorys Universe.
- Contract limitations on how we may use aggregated, de-identified data.
- Explorys' business preference.

The Rule:

- An Authorized User **may not** use or further disclose any Therapeutic Dataset or the Explorys Universe other than as permitted under the **rules** established in each contract.

Why?

- This general acknowledgment alerts each User of contract restrictions around the use of the data.

The Rule:

- Only **Authorized Users** are permitted to use the Data Services or access Explorys Data.
- All use must be according to the **rules**.
- Authorized Users are **prohibited** from **sharing credentials**.
- Requests to **transfer** an Authorized User account may be submitted to Explorys. Transfers may incur a fee.

Why?

- Each Authorized User seat has certain costs associated with it.
- Auditing integrity must be preserved.

The Rule:

- Authorized Users are **prohibited** from **attempting to re-identify** information included in the Explorys Universe or any Therapeutic Dataset.
- Authorized Users are **prohibited** from **contacting** any individuals that may be identified from that information.
- Authorized Users are **prohibited** from **downloading** raw patient level data.

Why?

- This makes clear that keeping the data de-identified must be a priority, and that patient privacy is of utmost importance.

The Rule:

- Authorized Users may use Explorys Data only for **purposes** of research or public health activities or to create derivative analytic reports.

Why?

- This clarifies the narrow nature of the access rights to Explorys Data.

The Rule:

- When connecting to their organization's region of the Explorys Platform, a **VPN connection** or comparable secure connection is required.
- All virtual desktop interfaces (VDIs) must be **hosted in the continental United States**.
- Explorys Data **may not** be **stored outside the U.S.**

Why?

- Security best practices.
- Restrictions on where Explorys Data may reside.

The Rule:

- An Authorized User is **prohibited** from:
 - **aggregating** or combining Therapeutic Datasets with any other data or using Explorys Data in a centralized processing environment, except when (i) approved and documented by Explorys and (ii) performed within the Explorys environment; and
 - creating a **repository** of the Therapeutic Datasets or the Explorys Universe.

Why?

- Maintaining Explorys' statistical **de-identification** certification.
- The right to access Explorys Data is via a time-limited subscription.

The Rule:

- An Authorized User is **prohibited** from:
 - **identifying organizations** that are the source of Explorys Data; and
 - using Explorys Data to **reveal competitively sensitive data**.

Why?

- Explorys' relationships with Providers in our network often include restrictions on re-identifying them.
- The nature of competitively sensitive data requires it to be handled with care.

The Rule:

- Subscribers must use appropriate **safeguards** to protect the Data Services from misuse.
- Subscribers must **report** misuse within five calendar days.

Why?

- Each organization is responsible for abiding by the rules and updating Explorys promptly of any issues

The Rule:

- Subscribers are **prohibited** from **marketing, selling, distributing, or sublicensing** the Data Services, except as permitted by the contract.

Why?

- The Data Services are available on a subscription basis, often by the seat.
- Explorys does not offer a license to the Data Services.

The Rule:

- Subscribers are **prohibited** from decompiling or **reverse engineering** the Data Services.
- Subscribers are **prohibited** from **exporting** the Data Services using the Data Services in **violation** of any federal, state, or local laws.

Why?

- The first prohibition protects the intellectual property of Explorys.
- The second prohibition establishes Explorys' expectation of legal compliance.

The Rule:

- During any **Evaluation Period**, an Authorized User may only use the Data Services for a “Permitted Purpose” which has been identified in writing.

Why?

- Evaluation Periods are intended to be trial subscriptions.

The Rule:

- Additional rules apply to **file sharing capability**.
 - **Training** is required.
 - Only **derivative analytic reports** may be downloaded.
 - Systems accessed must be based in the **U.S.**
 - **File sizes** are capped and may not be circumvented.
 - A subscriber **may not** cite the Providers who participate in the **Explorys Network** by organization name. A reference to the Explorys website is permissible.
 - **Reports / publications** citing the Explorys Network are subject to pre-approval by Explorys.

Why?

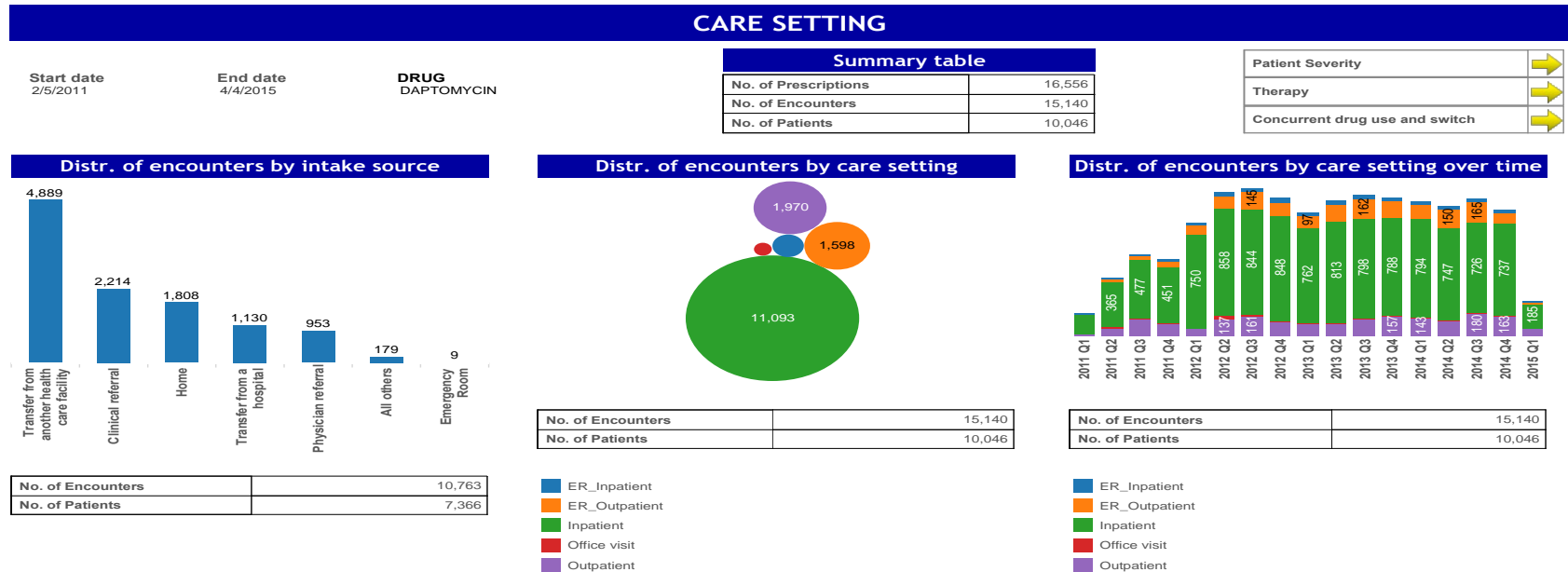
- No downloads of Explorys **Raw** Data are permitted.
- Integrity of Explorys' statistical certification.
- Certain contractual restrictions must be passed down.

More on file sharing:

- Explorys **audits** the files that are shared for compliance with the rules and restrictions.
- In the event of non-compliance, a **suspension** of file sharing rights may result.

Acceptable file download example:

These charts and graphs represent aggregate analytics



Prohibited file download example: Raw patient data

PATIENT IDENTIFICATION TOOL

Drug
VANCOMYCIN

Diagnosis
SEPT

Procedure
SURGERY

PATIENT SELECTOR

| Patient id | AGE | GENDER | |
|------------|-----|--------|--|
| 3078967 | 67 | M | |
| 3080243 | 56 | M | |
| 3084123 | 65 | F | |
| 3085579 | 49 | F | |
| 3092075 | 75 | M | |
| 3093455 | 54 | M | |
| 3095279 | 13 | F | |
| 3095843 | 84 | M | |
| 3112541 | 53 | M | |
| 3112766 | 43 | M | |

Type the Patient id here



Explorys patient id
3,078,967

Remediation for Violations of File Sharing

- File Sharing rights will be immediately suspended for users who are non-compliant.
- Downloaded raw data must be deleted.
- Users with first time violations must undergo supplemental training for further education on permissible downloads.
- File sharing rights will be permanently suspended for subsequent violations *except* in cases where it was not apparent that raw data was being downloaded along with aggregate data.

**In the event of questions,
please contact your Administrator.**