



Explore real-world, real-time global data



Feasibility Assessment on Pediatric low-grade Glioma

Data Entry Guide

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An aerial photograph of a dense green forest. A winding road, highlighted with orange lines, curves through the trees. Several points are marked with orange dots and labeled with alphanumeric codes: E11.9, N28.9, Z91.15, N17.9, and T86.10. The text 'Purpose of this Guide' is overlaid in the center in a large, white, sans-serif font.

Purpose of this Guide

● E11.9

● N28.9

● Z91.15

● N17.9

● T86.10

1. Purpose of this Guide

- This guide is addressed to participants in our projects. It is designed to **facilitate the documentation** in our EDC (*electronic Data Capture*) system.
- For a **better overview**, we recommend that new participants read the guide in full first. The table of contents also allows experienced participants to **quickly look up relevant information**.
- This guide has been developed based on our many years of experience and is **updated on an ongoing basis**. We will send you the latest version of the instructions at the start of each survey.

An aerial photograph of a dense forest with a winding road. Several orange dots are placed along the road, each with a label: E11.9, N28.9, N17.9, T86.10, and 201.15. The text 'Feasibility Assessment Pediatric Low-Grade Glioma (pLGG)' is overlaid in white on the center of the image.

Feasibility Assessment Pediatric Low-Grade Glioma (pLGG)

• E11.9

• N28.9

• N17.9

• T86.10

• 201.15

2. Feasibility: Pediatric Low-Grade Glioma (pLGG)

2.1 Focus of Data Collection

- This feasibility assessment serves as preparation for an ECA (external control arm) on pLGG, or as a starting point for the further collection of retrospective patient and therapy data in a detailed, indication specific electronic documentation form.
- The focus of the feasibility assessment is particularly on:
 - **Epidemiological metrics:** Patient count of the treated incidence of pLGG patients and targeted patient subgroups.
 - **Availability of retrospective treatment data:** Identification of available patient-related data in your patient records.
 - **Feasibility estimation:** Self-assessment of available personnel and time capacities with regard to potential participation in the ECA.

2.2 Data Collection Period

Please enter the aggregated data of your patients covering the period from **January 1st 2017 through December 31st, 2025.**

An aerial photograph of a dense green forest. A winding road, highlighted with orange lines, curves through the trees. Several orange dots are placed along the road, each with a label: E11.9, N28.9, Z91.15, N17.9, and T86.10. The text 'Getting Started in the Documentation System' is overlaid in the center in a large, white, sans-serif font.

Getting Started in the Documentation System

● E11.9

● N28.9

● Z91.15

● N17.9

● T86.10

3. Getting Started in the Documentation System

3.1 Log-in

1. Click on the link to the online documentation:

[Feasibility pLGG](#)

2. Enter your **User ID** and **password**:

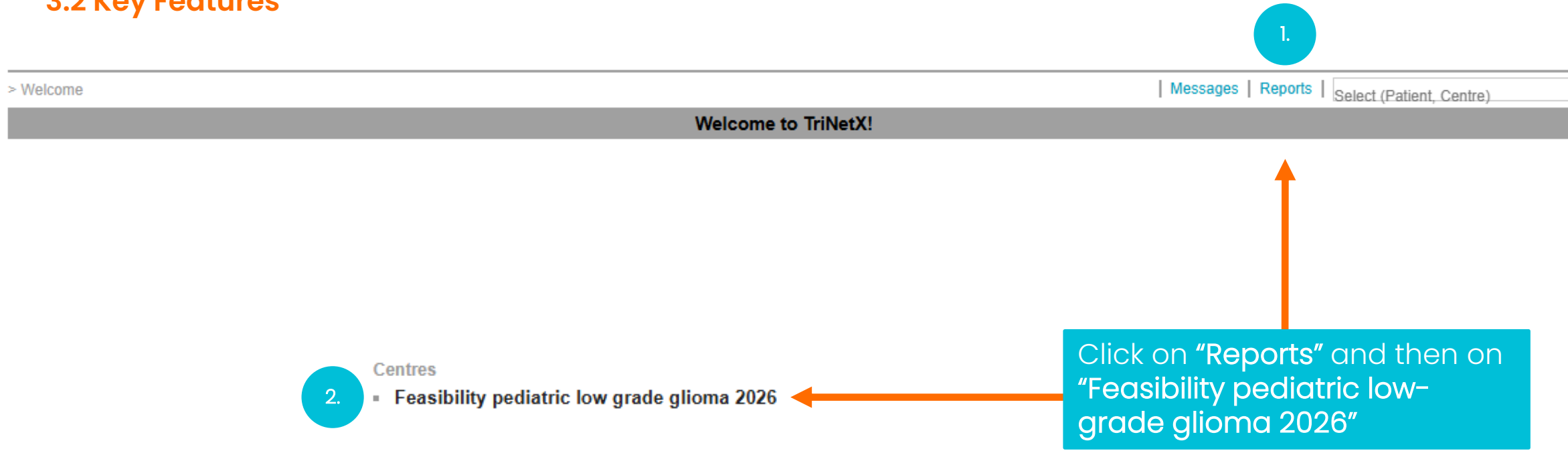
Upon registration, you will receive your User ID and an initial password from TriNetX Oncology via email. You must change the initial password to a password of your choice when you log in for the first time.

You can select your preferred language here





3. Getting Started in the Documentation System

3.2 Key Features



2. First steps in the documentation system

2.2 How to Get to the Questionnaire

Feasibility pediatric low grade glioma 2026		
Display the following states: <input checked="" type="checkbox"/> Completion status <input checked="" type="checkbox"/> Review / Frozen <input checked="" type="checkbox"/> Queries <input checked="" type="checkbox"/> Comments		
▶ Filter by:		
<input type="button" value="Apply"/> <input type="button" value="Reset"/>		
Centre	Σ	Feasibility pediatric low grade glioma 2026
zTNXO - Test LGG17		

Click on your Site ID

Important:

The icons and symbols provide information on the completeness of the data and the status of the queries. For detailed explanation of the icons and symbols see [Slide 17](#).

An aerial photograph of a dense green forest. A winding road, highlighted with orange lines, curves through the trees. Several orange dots are placed along the road, each with a label: E11.9, N28.9, Z91.15, N17.9, and T86.10. The text 'Navigation in Documentation Form' is overlaid in the center in a large, white, sans-serif font.

Navigation in Documentation Form

● E11.9

● N28.9

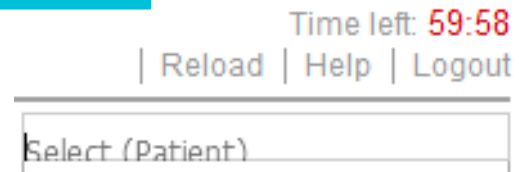
● Z91.15

● N17.9

● T86.10

4. Navigation in Documentation Form

The remaining session time is displayed at the top right of the page.

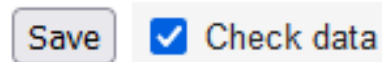


Important:

After 60 minutes of inactivity, an automatic log-out occurs for security reasons.

Please save your entered data regularly to prevent unwanted data loss!

At the bottom of the page, you will find the following buttons:



Note:

The data entered in the form will only be saved after you have clicked on "Save".

If you do not yet have all the required information, please uncheck the "Check information" box so that the incomplete form can be saved.

Please complete the missing information as soon as you have it.

Query-Management

● E11.9

● N28.9

● Z91.15

● N17.9

● T86.10

5. Query Management

5.1 Multi-Level Quality Control – Automated Check

Feasibility pediatric low-grade glioma 2026 Document-No. 3 - 3

Please correct the marked invalid data.

Input required.

Demographics
(e.g. Age, Sex)

< Please choose > *

Validation on Saving

After saving, the system automatically checks the entered data. Implausible values and missing mandatory fields will be highlighted in the form..

Warning "Invalid Data"

This message indicates that the data entered has not yet been saved. If the relevant data is not currently available to you, uncheck "Check data" (at the bottom of the page), save the form again, and add the missing information at a later time.

Save Check data

5. Query Management

5.1 Multi-Level Quality Control – Individual Review

Central Data Review

The documented data will be centrally reviewed by TriNetX Oncology for consistency and completeness.

In case of questions you will receive a query via email.

You can open the associated query text in the form by clicking on the red question mark next to the relevant question.

The image shows two screenshots of a web application interface. The top screenshot is a grey box containing a question: "5. Is the following information captured in your data?". A red question mark icon is circled in orange. Below the question is a note: "Note: Please provide a qualitative estimate of the % of patients for whom the data point is accessible within your data. You can find a list of additional example variables and tumor locations under the 'Help' button." Below the note is the text "Demographics (e.g. Age, Sex)" and a dropdown menu with the text "< Please choose >". An orange arrow points from the circled question mark to the bottom screenshot.

The bottom screenshot is a browser window titled "ST - DataCapture - 6.8.0.14 Queries and answers (TrinetX...)". The address bar shows "https://asp.interactive-systems.de/apps/WebObjects/ST49-productiv...". The page content shows a "Query" section with "Document-No. 3 - 3". Below this is the same question "5. Is the following information captured in your data?" with "Demographics" listed. A red question mark icon is circled in orange. Below the question is the text "Please complete the missing details. Please enter your answer here:" and a text input field. At the bottom are buttons for "Answer Query", "Cancel", and "Save".

5. Query Management

5.1 Multi-Level Quality Control – Individual Review

You have two options for responding to queries:

1. Correct / complete the data field in the form.
- or
2. Enter an explanation in the query text field and save it.

1.

5. Is the following information captured in your data?

Note: Please provide a qualitative estimate of the % of patients for whom the data point is accessible within your data. You can find a list of additional example variables and tumor locations under the "Help" button.

Demographics
(e.g. Age, Sex)

< Please choose >

Important

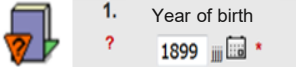





Should you adjust the data field and additionally leave an explanation in the query window, it must be saved in the query window and additionally the 'Save' button must be clicked at the end of the form.

2.

The screenshot shows a web browser window titled "DataCapture - 6.8.0.14 Queries and answers (TrinetX...)". The URL is "https://asp.interactive-systems.de/apps/WebObjects/ST49-productiv...". The page displays a "Query" window for "Document-No. 3 - 3". The query text is "5. Is the following information captured in your data?". Below this, the "Demographics" section is expanded, showing a patient record for "M#21 ? Maria Friese" with a timestamp of "08.04.2026 - 11:29:27 (CEST)". A text field with the placeholder "Please complete the missing details. Please enter your answer here." is highlighted with an orange oval. Below the text field are three buttons: "Answer Query", "Cancel", and "Save".

5. Query Management

5.2 Helpful symbols and icons

Icon/Symbol	Meaning
	<p>You can recognize an open query by the question mark</p>
	<p>You can recognize a query you have answered by the exclamation mark.</p>
	<p>You can recognize the data change or data confirmation that has been checked and accepted by the monitor by the tick: The query has been closed.</p>
	<p>A half-filled documentation sheet, indicates that not all forms in the sheet have been completed. However, this is often the case, e.g. if certain therapy steps within a therapy line have not yet been carried out.</p>
	<p>The exclamation mark on the documentation form indicates mandatory fields that must be completed.</p>
	<p>A documentation sheet that has been finally reviewed by the monitor is blocked for further data entry. You can identify this by the green flag.</p>

5. Query Management

5.3 Query management process

