

Is the GTI App difficult to use?

Loading data is easy – and quick. Completing the 9 modules can be done all at once or as patient data become available. The GTI app handles all calculations as data are entered and lets you know if you are missing any data. Although the timing of data collection will vary according to the specific trial or study, with the GTI app each patient visit can be recorded in a minute or two.

How long does it take to get scores from the GTI App?

GTI scores are in your hands as soon all required data are complete.

What is the protocol for using the GTI App during the study workflow?

The best practice is to share the work, to ensure efficient and accurate data capture.

Study Coordinator or Nurse:

Step 1. Updates any changes in the subject's medications for the treatment of hyperglycemia, hyperlipidemia, and hypertension.

Step 2. Weighs the subject, records the subject's height (at only the first visit), and measures the subject's vital signs.

Step 3. Records the results of laboratory tests that are relevant to the GTI, specifically the hemoglobin A1c (HgbA1c) and low-density lipoprotein (LDL) measurements, as well as the results of bone mineral density studies. Results of these tests may not be available at the time of the Trial Visit but should be completed by the Study Coordinator as the results become available.

The Physician Investigator:

Step 4. Examines the subject, gathering data required for the scoring of the remaining Domains, namely:

- Steroid Myopathy
- Skin Effects
- Neuropsychiatric Impact

- Infection
- Other Toxicities

The data can be captured easily over the course of a routine study visit, requiring only focused history-taking skills and a directed physical examination.

What is the cost to my organization to use the GTI App vs the Pen & Paper version?

Both Pen & Paper version and the GTI App require the purchase of a license. Each license and its fees are tailored to the design and size of the clinical trial. The Pen & Paper version has lower front end license fees but requires additional time and staffing to use it in a trial. The the GTI **App** license fees are higher but the app saves hundreds of hours of time and money.

Is the GTI App better than the pen & paper GTI?

YES. The App is built on the same index and logic of the Pen & Paper version of the GTI, but the App's features standardize the collection of data across each clinical trial, guard against errors in data entry, include logic checks, guarantee data completeness, and ensure scoring accuracy. The Pen & Paper version, an excellent tool constructed on the same principles as the App, that requires time and staffing, without which inconsistencies may affect the data collection and reporting.

Does the Physician Investigator need to complete all the data at every visit?

No. One of the strengths of the GTI is that more than half of the modules can be completed by the study coordinators. The study coordinators enter all the GTI data pertaining to the subject's medications, vital signs, routine laboratory work, and bone mineral density study results; in short, five of the GTI's nine domains.

Can data from a previous visit be changed or updated after the visit has been completed?

Yes, of course - with exceptions designed into the coding to maintain the integrity of the calculations and protect the accuracy of the scoring.

Why is no GTI score calculated at the Baseline Visit?

The GTI measures **change** in glucocorticoid (GC) toxicity. Therefore, a score can be derived only when comparing values from one visit to the next. Data related to GC toxicity are captured at Baseline, but GTI scores are calculated at designated follow-up visits, when GTI data are required by the protocol.

How do I know that the data I enter is accurate?

The generation of baseline data for most of the GTI Domains is straightforward:

- 1) The numerical values for medications, labs, vital signs, and bone mineral density are quantitative.
- 2) The other modules - steroid myopathy, skin, neuropsychiatric, infections, and other toxicities - are semi-quantitative, relying upon an evaluation by the physician-investigator.

Does the GTI App improve the process of studying steroid toxicity?

Yes. The App reinforces rigorous use by prompting both the study coordinator and physician investigator to complete the modules in an intuitive order. The GTI app incorporates the GTI Domains and the Additional Manifestations List logically and thoroughly.

How is GTI Score calculated?

GTI data are analyzed in two ways:

Cumulative Worsening Score (CWS)

For trials in some diseases, it may be most important to document ANY cumulative GC toxicity that occurs. The CWS assesses cumulative toxicity, both permanent and transient, thereby serving as a record of toxicity.

Aggregate Improvement Score (AIS)

In a trial anticipating that many patients will have some GC toxicity (or a lot of GC toxicity) at baseline, the AIS establishes that the new therapy is effective at reducing baseline toxicity over time. With the AIS, GC toxicities are deleted if they resolve - leading to an improvement in the score - and are added in the event of worsening.

Which GTI Score do we use for our trial?

Both scores are useful and both provide important information. Together, the CWS and AIS provide a granular and consistent judgement of how subjects in one group have fared with GC toxicity compared to subjects in another group.