Is the GTI App difficult to use?

Loading data is quick and easy and each patient visit can be recorded in the GTI in a minute or two. Completing the 9 modules can be done at once or as patient data become available. The GTI app handles all calculations as data are entered and lets you know what data may be missing.

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

GTI scores are in your hands as soon as you have entered all required data.

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.

Trial Coordinator or Nurse:

Step 1. Updates any changes in the subject's Glucose, Blood Pressure and Lipid medications.

Step 2. Records Height, Weight and Vital Signs.

Step 3. Records laboratory test results relevant to the GTI: hemoglobin A1c (HgbA1c) and low-density lipoprotein (LDL) measurements, and in come trials, bone mineral density BMD. Results of these tests may not be available at the time of the Trial Visit but should be entered 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?

Use of the GTI requires a license. Each license and its fees are tailored to the design and size of the clinical trial.

Is the GTI App better than electronic CRFs?

Yes. The App integrates into trial databases to ensure standardized collection of data across each clinical trial, guards against errors in data entry, includes logic checks, guarantees data completeness, and ensures scoring accuracy. The algorithms account for nuances that a trial team cannot always capture.

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

Not at all. One of the strengths of the GTI is that 5 of the 9 modules can be completed by the Trial Coordinator: those pertaining to medications, vital signs, routine laboratory work, and bone mineral density study results.

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

Yes but: some coded exceptions designed to maintain accuracy of the calculations and protect the integrity of the scoring.

Why is no GTI Score calculated at the Baseline Visit?

The GTI measures <u>CHANGE</u> in glucocorticoid (GC) toxicity over time. 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 only at follow-up visits.

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

The App helps you. The generation of baseline data for most of the GTI Domains is straightforward and the app includes a knowledge base with images and standardized definitions to promote rigor and accuracy.

1) The input for medications, labs, vital signs, and bone mineral density are numerical/quantitative.

2) The input for steroid myopathy, skin, neuropsychiatric, infections, and other toxicities - are semi-quantitative, and require 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 Trial 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 the GTI Score calculated?

GTI data are analyzed in two ways:

Cumulative Worsening Score (CWS)

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

Aggregate Improvement Score (AIS)

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 study arm have fared with GC toxicity compared to subjects in another arm.