STERITAS GTI Glucocorticoid Toxicity Index

An essential clinical outcome assessment for measuring steroid-toxicity

The competitive edge you need for approval and adoption of your new steroid-sparing therapeutic rests on quantifying glucocorticoid toxicity in your clinical trial. The Steritas GTI is the only composite clinical outcome assessment (COA) that measures steroid-toxicity directly. The Steritas GTI demonstrates safety and efficacy of steroid-sparing treatments.

The first-in-class COA is available through a digital platform engineered for the fast, accurate, and seamless calculation of steroid scores across several essential health domains.

- · Developed by 20 world experts across multiple sub-specialties
- FDA 21 CFR Part 11 enabled Software as a Medical Device (SaMD)
- · HIPAA compliant digital platform, cloud-based or on-premise deployment

Reduction in steroid-toxicity as measured by the Steritas GTI constituted the key secondary endpoint in the ADVOCATE trial for the use of avacopan in the treatment of ANCA-associated vasculitis. The drug was granted regulatory approval in the United States, Europe and Japan. The FDA and European Medicines Agency view steroid reduction as a reflection of both efficacy and safety.

When you license the Steritas GTI you have access to our modern cloud-based technology stack when and where you need it.

Our Support Team is at your side.

From the moment you license the Steritas GTI our team becomes part of your team throughout your entire clinical trial.

Our support

- Introductory meeting with your entire trial team
- Ongoing support with customizable trial materials
- Guidance for translations, e-COA migration, EDC, DDC, and other integrations

Additional offerings

- Customized training for investigator meetings and trial design consultation
- Digital strategies and engineering support for your data management team
- Global network of immune-mediated and inflammatory disease experts

The Steritas GTI will help demonstrate safety and efficacy of your new steroid-sparing therapy. Our experts will be at your side every step of the way.

To register your interest, please complete our form.

STERITAS GTI Subject ID: patient 12345 -* change Solgiect				\$ (0)	
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GTI Menu 🛛 M	lissing GTI D	ata	SteriTox Profile	Visit Date: 07/10/18	
he calculated GTI scorr revious visit. Only the l Composite GTI	e measures the highest weighte Current Visit Score	d item is sco Score to Date	stween the current visit and th red for each domain. Specific List	STERITOX	l
Body Mass Index		(CWS, AIS)		PROFILE	
Minor improvement in BMI	-21			Calculated Result	
Glucose Tolerance		0, 0		Cumulative Worsening Score 59	
Major improvement ir glucose tolerance	-44		Diabetic Neuropathy	Aggregate Improvement -77 Score	
Blood Pressure		0, 0		Score	
Major improvement in blood pressure	-44				
Lipids		0, 0			
No change	0		Y		W
Bone Density		0, 0		STERIT	JX
Minor worsening of bone density	29		BMD Decreased	PROFILI	
Steroid Myopathy		0, 0			
Minor improvement	-9			Calculated Res	ult
Skin Toxicity		0, 0			
Minor improvement in hirsutism	0			Cumulative	
Moderate improvement in acneiform rash	-18			Worsening Score	59
Neuropsychiatric 1	oxicity	0, 0			
Minor worsening of insomnia symptoms	11			Aggregate Improvement	-7
Infections		0, 0		Score	
Moderate worsening of infection	19				
Other					