

CSSC 004  
 Protocol v10.0, dated October 20, 2021  
 Summary of changes as compared to protocol July 6, 2021

This protocol v10.0 (dated October 20, 2021) replaces protocol v9.0 (dated July 6, 2021) and incorporates the following changes. Administrative changes such as typographical, grammatical, editorial corrections are not documented here but are indicated within the protocol using tracked changes. All page numbers correspond to the tracked changes copy of protocol dated July 6, 2021.

Page(s)	Section	Used to read	Now reads	Reason
All	Header	CSSC-004 Version 9.0 July 6, 2021	CSSC-004 Version 10.0 October 20, 2021	Updated version date
42	1.3 Reporting Process – Assessment of Association	The association assessment categories that will be used for this study are: Associated – The event is temporally related to the administration of the study product and no other etiology explains the event. Not Associated – The event is temporally independent of the study product and/or the event appears to be explained by another etiology.	Is the event related to investigational treatment categories to be used for this study are: <ul style="list-style-type: none"> <li>• Not related</li> <li>• Unlikely</li> <li>• Possible</li> <li>• Probable</li> <li>• Definite</li> </ul>	Updated to reflect assessment categories used by committee
44	7.1 Monitoring Plan	Ronald Rodriguez, MD., PhD Henry B. and Edna Smith Dielmann Memorial Professor of Urologic Science Doctor’s Hospital Renaissance Distinguished University Chair of Urology University of Texas Health Science Center at San Antonio  Pia Mikkelsen Lynch, M.D. President & Managing Director PML Medical Consulting, Aps. Denmark	Ronald Rodriguez, MD., PhD Henry B. and Edna Smith Dielmann Memorial Professor of Urologic Science Doctor’s Hospital Renaissance Distinguished University Chair of Urology University of Texas Health Science Center at San Antonio	Removed Pia Lynch, whose focus was CSSC-001

45	7.1 Monitoring Plan	Added new text	<p>A Clinical Events Committee (CEC) has been established by the Grant Principal Investigators consisting of three expert members, including the Chairman, without conflicts of interest to independently review Serious Adverse Events (SAEs) of patients who were hospitalized to evaluate the relatedness to COVID and the severity of hospitalization and determine clinical safety and efficacy outcomes. Any SAE event that does achieve consensus for hospitalization related to COVID or severity of hospitalization will be discussed with all three adjudicators to review definitions and provide any other documentation for that event that may assist in achieving consensus. If non-consensus remains, Dr Rodriguez, CEC Chairman will have the deciding vote.</p> <p>Ron Rodriguez, MD Member and Chairman Virology and Trial Safety</p> <p>Joanna Daily, MD Member Microbiology and Immunology</p> <p>Panagis Galiatsatos, MD Member Pulmonary and Critical Care Medicine</p>	<p>Providing description of the Clinical Events Committee; organized to independently review SAEs that result in hospitalizations.</p>
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