The YODA Project Research Proposal Due Diligence Assessment

Date:	Part 1: General Information			
Product Name: Golimumab Therapeutic Area: Immunology Product Class: Antirheumatic Agents - Biologic Response Modifiers Condition(s) Studied: Active Ulcerative Colitis Protocol Number(s) and Title(s): Active Ulcerative Colitis Protocol Number(s) and Efficacy of Golimumab Induction Therapy, Administered Subcutaneously, in Subjects with Moderately to Severely Active Ulcerative Colitis NCT00488631 - C0524T18 - A Phase 3 Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Safety and Efficacy of Golimumab Induction Therapy, Administered Subcutaneously, in Subjects with Moderately to Severely Active Ulcerative Colitis NCT00488631 - C0524T18 - A Phase 3 Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Safety and Efficacy of Golimumab Maintenance Therapy, Administered Subcutaneously, in Subjects With Moderately to Severely Active Ulcerative Colitis Part 2: Data Availability Data Holder has authority to provide clinical trial data or development partner Assagreed to share clinical trial data. Comments: Data Holder has sharable electronic clinical trial data or data can be converted Yes to electronic format. Comments: De-identification and redaction of clinical trial data in accordance with current Yes HIPPA and EU criteria allows protection of participant privacy and confidentiality. Comments: De-identification and relevant indication studied has either been approved by Yes regulators in the US and EU, or terminated from development. Comments: Data Holder has completed the clinical trial and trial has been completed for a Yes period of at least 18 months (or results published in peer-reviewed biomedical literature). Comments: Part 3: Data Availability Summary Based on the responses to the above Data Availability Guestions, the Yes requested clinical trial data are available for a data sharing request. Part 4: Proposal Review Question: Question: Question: No No	YODA Project (Protocol) ID:	2020-4397		
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