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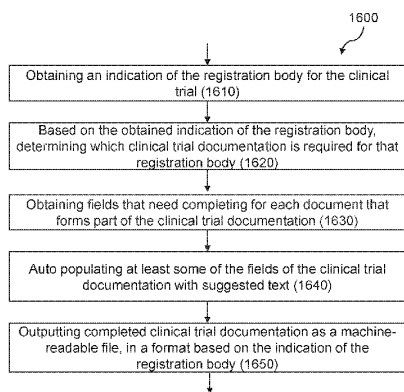
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(54) Title: COMPUTER-IMPLEMENTED METHOD FOR THE PROCESSING AND/OR CREATION OF CLINICAL TRIAL PROTOCOL DOCUMENTATION



(57) Abstract: Disclosed herein is a computer-implemented method for the processing and/or creation of clinical trial protocol documentation. The method comprises obtaining an indication of the registration body for the clinical trial; obtaining fields that need completing for each document that forms part of the clinical trial documentation; auto populating some of the fields of the clinical trial documentation with suggested text; and outputting completed clinical trial documentation as a machine-readable file, in a format based on the indication of the registration body. The method may additionally comprise outputting "smart" documents for use in a trial master file.

Figure 15