

IMPAACT Manual of Procedures
Overview of Section Contents and Identification of Current Section Versions

Section	Current Version	Comments
Section 1 Overview of IMPACT Network	Not Yet Available	
Section 2 IMPAACT Leadership	Not Yet Available	
Section 3 IMPAACT Operational Components	Not Yet Available	
Section 4 IMPAACT Protocol Teams	Not Yet Available	
Section 5 Community Partnership	3 October 2017	<ul style="list-style-type: none"> • Added details related to regional and site representation on the ILG to Section 5.3.2
Section 6 Network Meetings and Communications	7 April 2017	
Section 7 General Policies and Procedures	Not Yet Available	
Section 8 Human Subjects Considerations	Not Yet Available	
Section 9 Protocol Development and Modifications	17 March 2017	<ul style="list-style-type: none"> • Updated links throughout • Clarified procedures in Section 9.1.3 related to SLG review of capsules • Updated expected timelines in Table 9-1 and Sections 9.3.3 and 9.3.5.3 • Clarified implementation requirements for CM and LoA if updates to implementation materials are needed in Sections 9.4.1 and 9.4.2 • Other minor clarifications and revisions throughout
Section 10 Site Selection for IMPAACT Studies	12 August 2016	
Section 11 Study Specific Pre-Implementation Activities	31 January 2018	<ul style="list-style-type: none"> • Added recipients to open to accrual notification in Section 11 • Updated Section 11.1.6 to reflect sign-off requirements for eCRF changes • Updated training language in Section 11.2.3

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Section 12 Study Implementation	10 April 2017	<ul style="list-style-type: none"> • Updated language related to case report forms in Section 12.2.2 and queries and reports in Sections 12.3.3 and 12.3.4, consistent with new data management systems (i.e., Rave) • Other minor clarifications and revisions throughout
Section 13 Study Oversight	12 August 2016	
Section 14 Study Close-out	Not Yet Available	
Section 15 Ancillary Studies and Investigations	12 August 2016	
Section 16 Training	Not Yet Available	
Section 17 Laboratory Considerations	22 March 2017	
Section 18 Network Evaluation	12 August 2016	
Section 19 Publications Requirements and Procedures	26 May 2017	<ul style="list-style-type: none"> • Revised language in Section 19.5 related to journal requests for data availability
Appendix I Unblinding Procedures	3 March 2017	<ul style="list-style-type: none"> • Updated Section I.6.1 to note treatment information communication methods may be made via email