Public Meeting on ICH E8(R1)- General Considerations for Clinical Studies
FDA Great Room, Building 31, Room 1503
10903 New Hampshire Avenue, Silver Spring, MD 20993-0002

October 31, 2019

DRAFT AGENDA OUTLINE

8:30 a.m. Welcome, Opening Remarks
8:45 a.m. Session I: The role of E8 as part of the ICH GCP Renovation, and next steps – 60 minutes

Presentations

10:00 a.m. Session II: Drug Development Plan – 60 Minutes

Presentation
Stakeholder Panelist Perspective
Public Input

11:00 a.m. Session III: Components of Study Design – 60 minutes

Presentation:
Stakeholder Panelist Perspective
Public Input

1:00 p.m. Session IV: Quality by Design/ Critical to quality factors – 90 minutes

Presentation:
Stakeholder Panelist Perspective
Public Input

2:45 p.m. Session V: Data sources – 90 minutes

Presentation
Stakeholder Panel Perspective
Public Input

4:15 p.m. Open Comment
4:45 p.m. Closing Remarks, Adjournment