

ICH M10 EWG Work Plan

January 30, 2019

Topic Adoption date: *June 2016*

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Regulatory Chair: *Dr. Brian Booth - FDA, United States*

Last Face-to-Face Meeting: *Charlotte, NC, USA, November 2018*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Oct. 2016</i>	<i>Concept Paper endorsement</i>
<i>Oct. 2016</i>	<i>Business Plan endorsement</i>
<i>Jan. 23, 2019</i>	<i>Step1 sign-off</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Feb. 2019</i>	<i>Step 2a, 2b endorsement</i>
<i>Mar. 2019</i>	<i>Public consultation (~Aug. 2019)</i>
<i>Nov. 2020</i>	<i>Step 3 sign-off and Step 4 adoption</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Mar. 2019	<i>Aug. 2019</i>	<i>Public consultation period</i>	<i>Regional regulatory consultation of M10 draft guideline is conducted in each Regulatory Member</i>
Sep. 2019	<i>Sep. 2019</i>	<i>E mail consultations</i>	<i>Comments obtained through the public consultation in each Member are shared within EWG members.</i>
Oct. 2019	<i>Oct. 2019</i>	<i>Teleconferences</i>	<i>Topics to be discussed in face-to-face meeting are selected and discussed.</i>
Nov. 2019	<i>Nov. 2019</i>	<i>Face-to-Face meeting</i>	<i>The draft guideline is revised by reflecting the comments obtained via public consultation.</i>