

ICH Q5A(R2) EWG Work Plan

January 28, 2022

Topic Adoption date: *May 2019*

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Regulatory Chair: *Dr. Johannes Blümel – EC, Europe*

Last Face-to-Face Meeting: *Singapore, November 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>May 2019</i>	<i>Endorsement of Concept Paper outline</i>
<i>Nov. 2019</i>	<i>Endorsement of Concept Paper and Business Plan</i>
<i>Nov. 2021</i>	<i>Circulation of Consensus First Team Draft</i>
<i>Jan. 2022</i>	<i>Submission of First Draft to PWP</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Apr. 2022</i>	<i>Major Revision to second team draft</i>
<i>Sep. 2022</i>	<i>Step 1 sign-off and Step 2 a/b endorsement</i>
<i>Feb. 2024</i>	<i>Step 3 sign-off and Step 4 adoption</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Jan. 2022</i>	<i>Apr. 2022</i>	<i>Multiple EWG Meetings via Teleconference</i>	<ul style="list-style-type: none">• <i>Continued discussion of key items</i>• <i>Small group drafting of revision based on team comments</i>• <i>Incorporation of feedback from PWP</i>• <i>Preparation for face-to-face meeting</i>

May 2022	<i>May 2022</i>	<i>Face to Face Meeting</i>	<ul style="list-style-type: none"> • <i>Focused discussion of key specific changes to be included in revision</i> • <i>Resolution of outstanding issues</i> • <i>Update material for presentations to external stakeholders</i>
Jun. 2022	<i>Jun. 2022</i>	<i>Multiple EWG Meetings via Teleconference</i>	<ul style="list-style-type: none"> • <i>Incorporation of final edits based on face-to-face discussion</i> • <i>Editing and review of consensus final draft</i>
Sep. 2022	<i>Sep. 2022</i>	<i>EWG Meeting</i>	<ul style="list-style-type: none"> • <i>Sign-off of Step 1 document</i>