

WORK PLAN Pharmacovigilance Working Group

Date: 28 October 2020

Co-Chair: Adel Alrwisan, SFDA, Saudi Arabia

Co-Chair: Geraldine Hill, Medsafe, New Zealand

1. Key Milestones and Deliverables

1.1. Current status of key milestones and deliverables

Past completion date	Objective	Key Milestone or Deliverable
<i>July 2020</i>	Review and approve the mandates	<i>Propose endorsement of the mandate</i>
<i>September 2020</i>	Meeting	<i>Meeting Minutes</i>
<i>September 2020</i>	Co-chair nomination	<i>Propose endorsement for a Co-chair</i>
<i>October 2020</i>	Meeting	<ul style="list-style-type: none"> • <i>Meeting Minutes</i> • <i>Proposed work plan</i>

1.2. Future anticipated key milestones and deliverables

Expected future completion date	Objective	Key Milestone or Deliverable
Stage 1		
<i>January 2021</i>	Define regulatory tasks and terminology relevant to PV	<i>Survey tool to collect PV regulatory activities, types of data sources, methods employed in PV using such data sources</i>
<i>Early February 2021</i>	As above	<i>Survey tool sent to participants to complete</i>
<i>March/April 2021</i>	As above	<i>Survey responses compiled</i>
<i>October 2021?</i>	Compile inventory of regulatory activities, data sources and methodologies	<i>Compendium of PV terminologies, activities, data sources and methodologies</i>

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
<i>October 2020</i>	<i>November 2020</i>	<i>Complete work plan</i>	<ul style="list-style-type: none"> - <i>Draft work plan to be finalised by WG by 30 October 2020</i> - <i>Presentation of work plan to Management Committee Nov 2020</i>
<i>January 2021</i>	<i>Early February 2021</i>		<ul style="list-style-type: none"> - <i>Prepare survey tool to collect PV regulatory activities, types of data sources, methods employed in PV using such data sources</i>
<i>Early February 2021</i>	<i>Mid-February 2021</i>		<ul style="list-style-type: none"> - <i>Send survey tool to participants to complete</i>
<i>March/April 2021</i>	<i>October 2021</i>		<ul style="list-style-type: none"> - <i>Compile responses and prepare a compendium of PV terminologies, activities, data sources and methodologies</i>