

## Work Plan

### Pharmacovigilance Working Group

Date: 1 November 2021

**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

<b>Past completion date</b>	<b>Objective</b>	<b>Key Milestone or Deliverable</b>
<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"> <li>• <i>Meeting Minutes</i></li> <li>• <i>Proposed work plan</i></li> </ul>
<i>Jan 2021</i>	Meeting	<ul style="list-style-type: none"> <li>• <i>Meeting minutes</i></li> <li>• <i>Propose survey areas</i></li> </ul>
<i>April 2021</i>	Meeting	<ul style="list-style-type: none"> <li>• <i>Meeting minutes</i></li> <li>• <i>Review and endorse the survey</i></li> <li>• <i>Revise workplan</i></li> </ul>

##### 1.2. Future anticipated key milestones and deliverables

<b>Expected future completion date</b>	<b>Objective</b>	<b>Key Milestone or Deliverable</b>
<b>Stage 1</b>		
<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>December 2021</i>	As above	<i>Survey responses compiled</i>
<i>March 2022</i>	Compile inventory of	<i>Compendium of PV terminologies, activities, data</i>

	regulatory activities, data sources and methodologies	<i>sources and methodologies</i>
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## 2. Timeline for Specific Tasks

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
<i>October 2020</i>	<i>November 2020</i>	<i>Complete work plan</i>	<ul style="list-style-type: none"> <li>- <i>Draft work plan to be finalised by WG by 30 October 2020</i></li> <li>- <i>Presentation of work plan to Management Committee Nov 2020</i></li> </ul>
<i>January 2021</i>	<i>May 2021</i>	<i>Complete survey tool</i>	<ul style="list-style-type: none"> <li>- <i>Prepare survey tool to collect PV regulatory activities, types of data sources, methods employed in PV using such data sources</i></li> </ul>
<i>May 2021</i>	<i>December 2021</i>	<i>Data collection</i>	<ul style="list-style-type: none"> <li>- <i>Send survey tool and collect responses to participants</i></li> </ul>
<i>January 2022</i>	<i>April 2022</i>	<i>Data analysis</i>	<ul style="list-style-type: none"> <li>- <i>Compile responses and prepare a compendium of PV terminologies, activities, data sources and methodologies</i></li> </ul>
<i>May 2022</i>	<i>August 2022</i>	<i>Report writing</i>	<ul style="list-style-type: none"> <li>- <i>Draft a report</i></li> </ul>