

Annual Public Workshop 2019, Day 3

AGENDA FOR INTERNATIONAL REGULATOR'S FORUM, APRIL 5, 2019

Time	Description	Speaker
9:00 - 9:30AM	<p>Overview of International Regulator's Forum</p> <ul style="list-style-type: none"> • Forum Logistics • Mobile app polling feature • Background and motivation • Learning objectives • ICH framework and publicly available data sources and tools 	<p>Anissa Ferguson <i>Food & Drug Administration</i></p> <p>Gerald Dal Pan <i>Food & Drug Administration</i></p> <p>Michael Nguyen <i>Food & Drug Administration</i></p>
9:30 - 10:30AM	<p>Part 1: How does FDA decide what safety issues to study?</p> <ul style="list-style-type: none"> • Case study of a safety concern emerging in the pre-approval setting • Interactive poll 	<p>Sarah Dutcher <i>Food & Drug Administration</i></p>
10:30 - 10:45AM	BREAK	
10:45 - 11:30AM	<p>Part 2: How does FDA decide what safety issues to study?</p> <ul style="list-style-type: none"> • Case study of a safety concern emerging in the post-approval setting • Interactive poll 	<p>Danijela Stojanovic <i>Food & Drug Administration</i></p>
11:30 - 12:30PM	LUNCH	
12:30 - 1:30PM	<p>Part 3: How does FDA decide what safety issues to study?</p> <ul style="list-style-type: none"> • Case study of a signal identification scenario • Framework for assessing the fitness of TreeScan with a regulatory objective • Communication of results • Alert follow-up 	<p>Michael Nguyen <i>Food & Drug Administration</i></p>

<p>1:30 - 2:30PM</p>	<p>How does FDA maintain its commitment to transparency and inform its stakeholders?</p> <ul style="list-style-type: none"> Principles of transparency, key vehicles (e.g., Sentinel website), touch points <p>How has Sentinel data been used in the regulatory process?</p> <ul style="list-style-type: none"> Range of regulatory outcomes to date Review of real-world examples 	<p>Sara Azimi-Bolourian <i>Food & Drug Administration</i></p> <p>Sarah Dutcher <i>Food & Drug Administration</i></p>
<p>2:30 - 3:00PM</p>	<p>How do I get my own large dataset?</p> <ul style="list-style-type: none"> Publicly available data sources and Sentinel data transformation tools Review of available ETL (extract, transform, load) code for MarketScan and Medicare data sources 	<p>Judith Maro <i>Harvard Pilgrim Healthcare Institute</i></p>
<p>3:00 – 3:15PM</p>	<p>BREAK</p>	
<p>3:15 - 4:15PM</p>	<p>Perspectives from CNODES (Canadian Network for Observational Drug Effect Studies) and CPRD (Clinical Practice Research Datalink)</p> <ul style="list-style-type: none"> International experience using the Sentinel data transformation code and analytic tools 	<p>Michael Paterson <i>ICES</i></p> <p>Achim Wolf <i>Medicines and Healthcare products Regulatory Agency</i></p> <p>Stephen Welburn <i>Medicines and Healthcare products Regulatory Agency</i></p>
<p>4:15 - 4:30PM</p>	<p>Meeting Wrap-Up</p> <ul style="list-style-type: none"> Feedback Survey 	<p>Anissa Ferguson <i>Food & Drug Administration</i></p>