



# Electronic Transfer of Safety Data

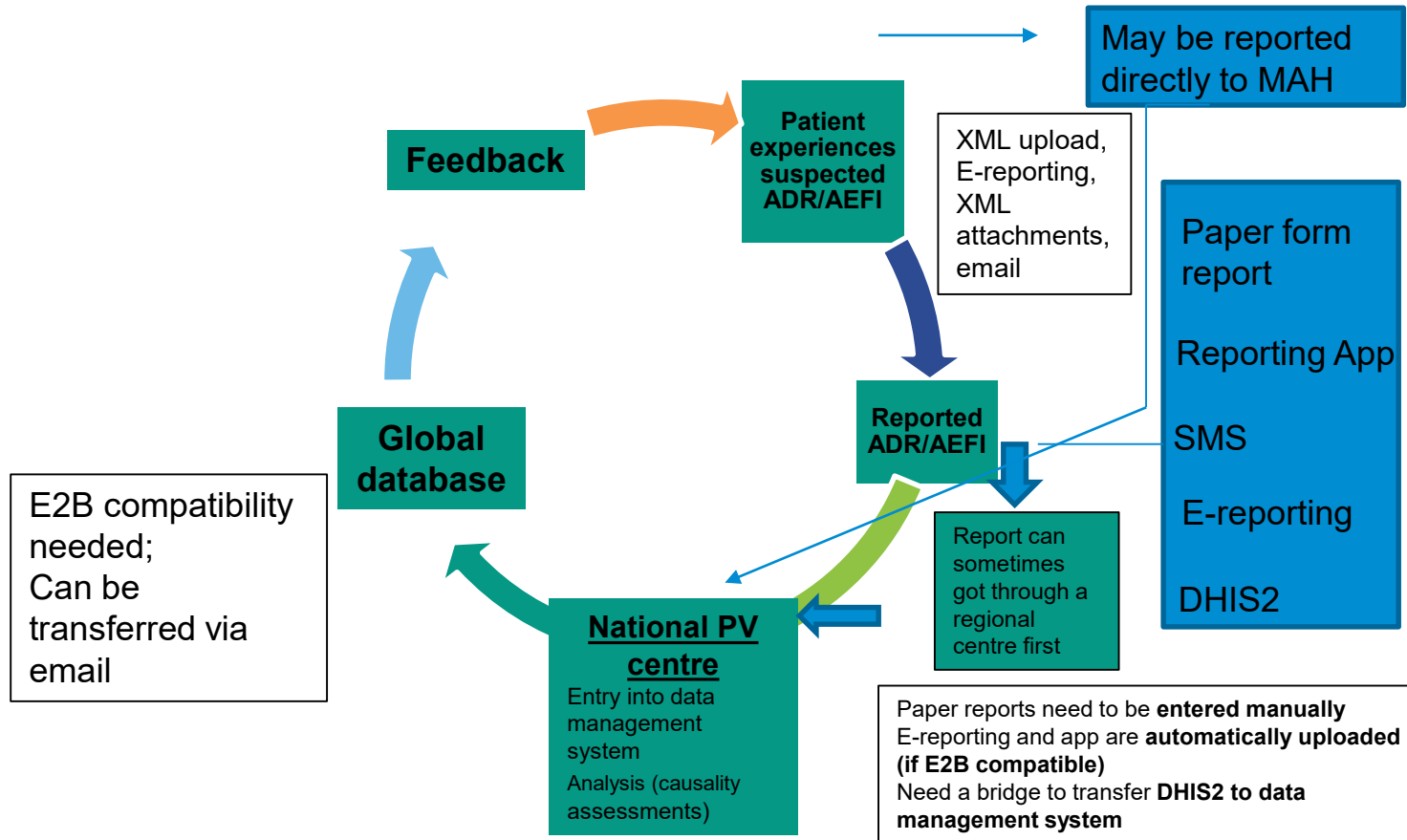
**Hiiti Sillo**

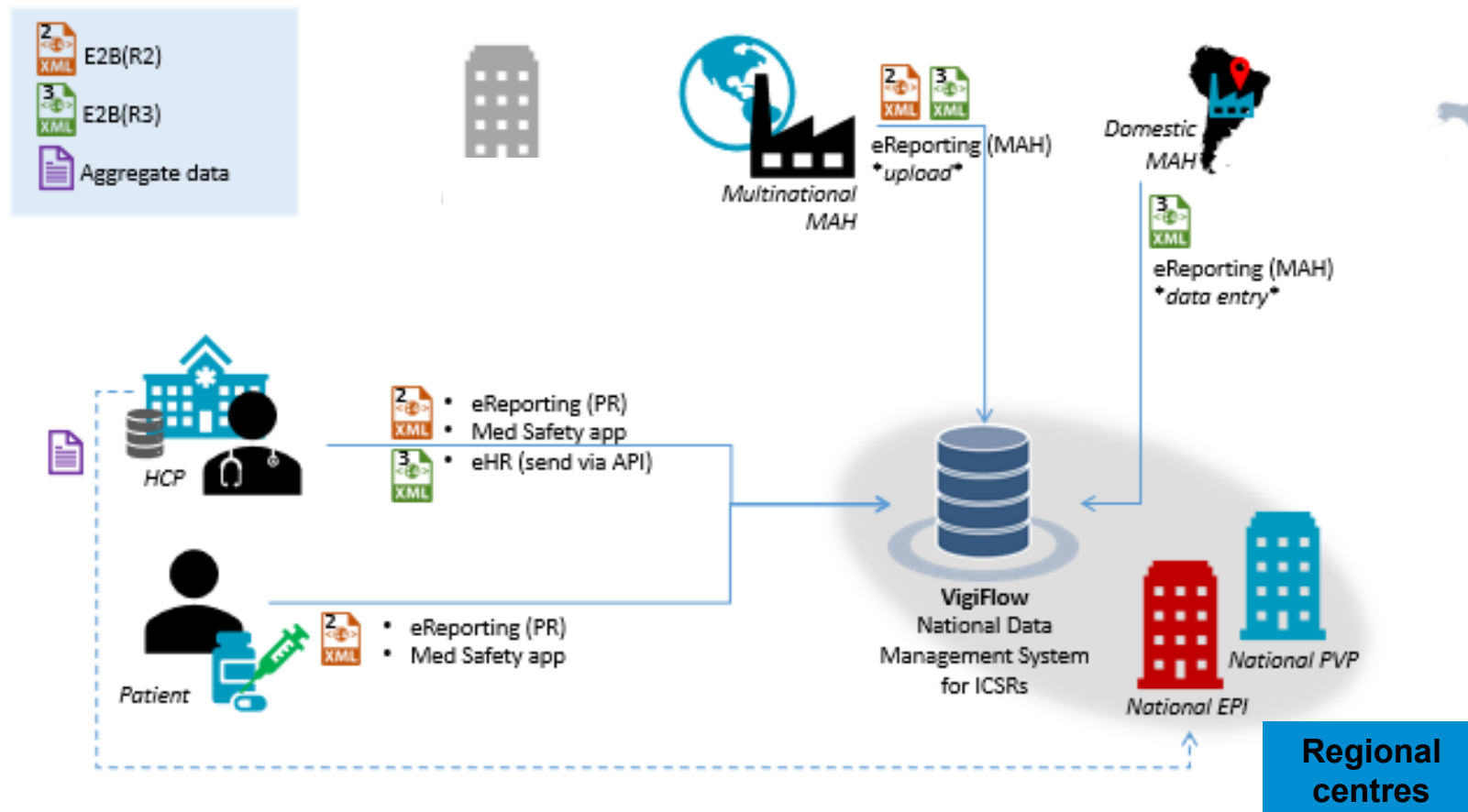
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2 December 2020

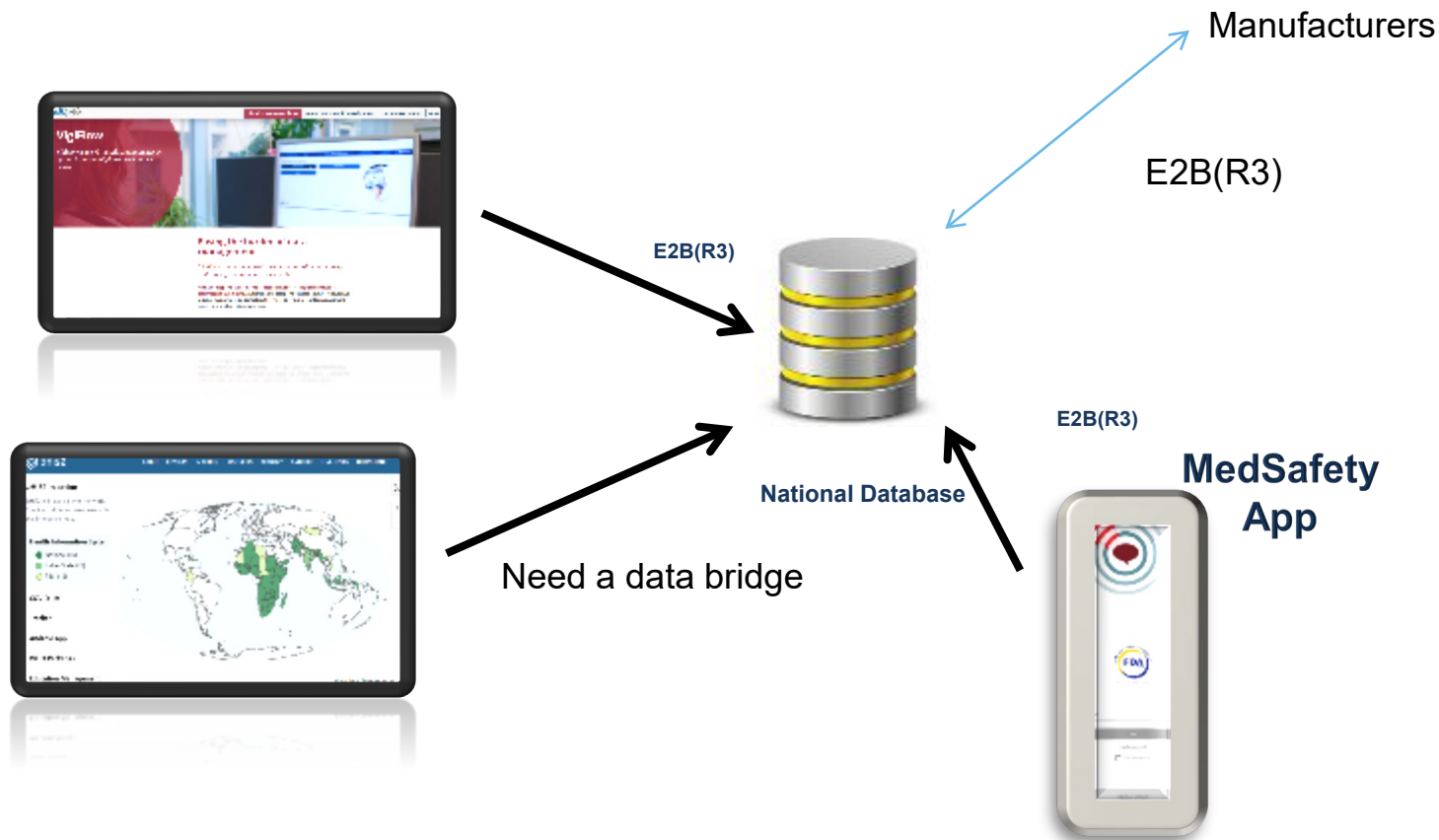


# Transfer of data

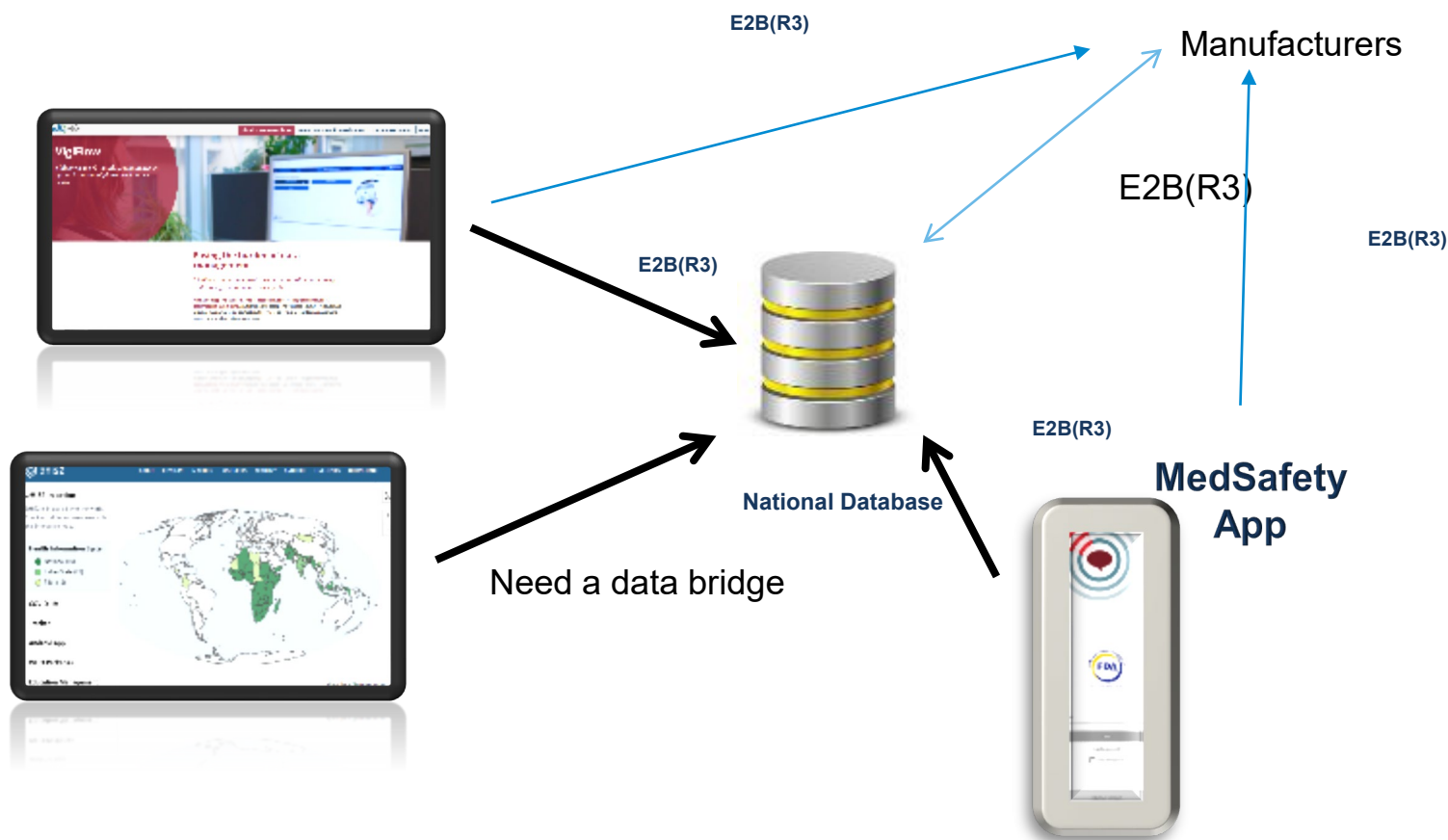




# Reporting tools



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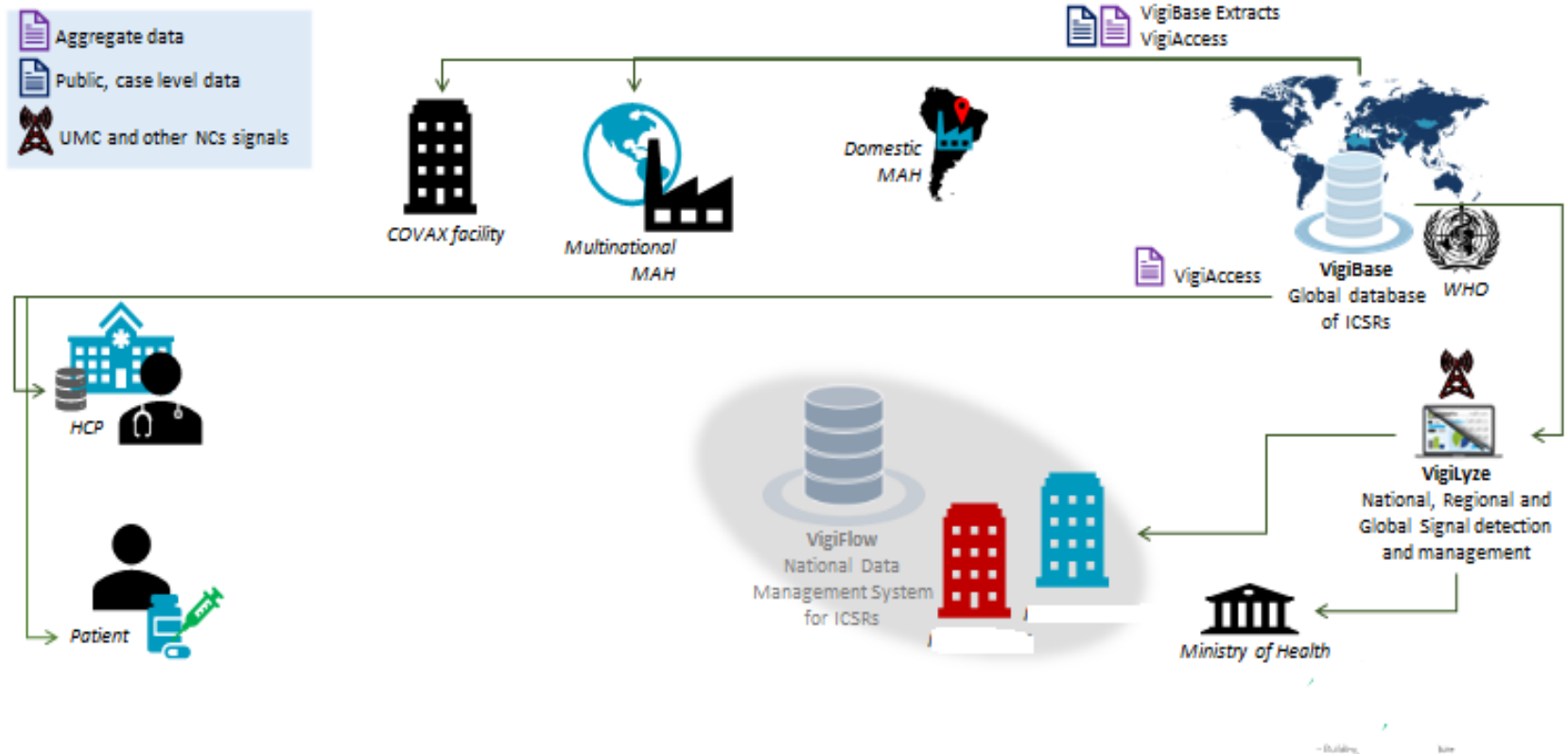


## Electronic collection of ADR/AE and AEFI data with VigiFlow

Source	Electronic channel options	Format	Transfer process	Alternative channels
<b>Patient</b> (primary reporter)	Data entry, eReporting <i>PR</i> Data entry, Med Safety app	E2B(R2) E2B(R2)	Automatic Automatic	Phone, SMS, Paper form
<b>HCP</b> (primary reporter)	Data entry, eReporting <i>PR</i> Data entry, Med Safety app Extract from eHR (AEFI/ICSR) (Data entry in VigiFlow)	E2B(R2) E2B(R2) E2B(R2/R3) E2B(R3)	Automatic Automatic Manual/Automatic ? -	Phone, SMS, Paper form, Fax
<b>Domestic MAH</b> (secondary reporter)	Data entry, eReporting <i>MAH</i>	E2B(R3)	Automatic	CIOMS forms (pdf, paper, fax...)
<b>Multinational MAH</b> (secondary reporter)	XML upload, eReporting <i>MAH</i> XML attachments, E-mail	E2B(R2/R3) E2B(R2/R3)	Automatic Manual	



# Electronic access to drug & vaccine safety information – global Stakeholders, Channels, Formats





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# Thank you