Global: Market Research and Patient Support Program Case Transmission Verification (CTV) Guidance and Form

This document includes the CTV form and additional guidance to support the implementation of Case Transmission Verification at the program level with the standards for the frequency of CTV which must be performed for Market Research Programs (MRPs) and Patient Support Programs (PSPs) (hereafter referred collectively as "MAP" [**M**arket Research **A**nd **P**atient Support Program]) as described in the corresponding *Global: Market Research and Patient Support Program Pharmacovigilance Compliance (SOP-0102065)*.

CTV is the process performed between the third party (e.g., Service Provider/Roche personnel) and Safety Unit in order to ensure that all adverse events (AE)/Special Situation Reports sent to Safety Unit have been successfully received by the Safety Unit.

The CTV form should be received before the 30 days completion timeline to ensure the Safety Unit can proceed with the reconciliation in the safety database, follow-up on any discrepancies and ensure results are documented in the MAP tracking system.

1.0 CTV frequency and timelines

Period Covered: Actual Start Date to Actual End Date

		Duration of MAP	
		Less than or equal to 3 months	**Greater than 3 months**
Minimum Frequency of CTV	**MRP**	End of program (Actual End Date)	Every 90 days (from Actual Start Date)
	PSP	End of program (Actual End Date)	Every 30 days (from Actual Start Date)

- *Timelines to complete and upload in the MAP tracking system: Within 30 calendar days from the CTV due date.*
- *The last CTV should cover the entire period from the previous CTV due date until the MAP Actual End Date.*

Note: Examples of driving factors where increased CTV frequency in on-going programs may be required include but are not limited to, number of patients enrolled, number of interactions, audit findings and late AEs. CTV ensures the confirmation of sending safety information by the party performing the program and receiving safety information at Roche.

To achieve compliance with these timelines, it is highly recommended that the Service Provider/Roche personnel sends the completed CTV form to the Safety Unit well in advance of the end of the timeline, for timely uploading in the MAP tracking system.

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2.0 CTV Form

Roche's Program Identification Number: *(e.g., MAP-GB-1234)*			
Country:		**Program Name:**	
Reporting Period:	From: To:		
Applicable Period of Time for Case Transmission Verification (CTV):	Periodic CTV ☐ Additional CTV ☐ Final CTV ☐		
Service Provider Name: *(if applicable)*			

Details of Person Completing the Form:

Name:		**Date:**	
Telephone Number:		**Email Address:**	

No Adverse Events (AEs) or Special Situation Reports were submitted to the Safety Unit in the reporting period listed above ☐

The following is a template that could be used to list any AEs and/or Special Situation Reports which have been submitted to the Safety Unit in the reporting period listed above.

Note: The below template could be sent in an excel format to Roche for the specified period and uploaded together with CTV form in the MAP tracking system. The below columns should be the minimum required fields to be completed during the CTV.

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Roche's Case Number *(Roche Use Only)*	Date AE Sent to Drug Safety	Service Provider Reference Number (if available)	Healthcare Professional / Caregiver's Name	Patient's Identifier(s)	Suspect Drug(s)	Adverse Event(s) / Special Situation Report(s)

<u>If any AEs/Special Situation Reports have been identified that were not reported to Roche, report them immediately and contact the Safety Unit</u>

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For Roche Use Only:

Date CTV Form was Reviewed:		**Name of Reviewer:**	

Case Transmission Verification

Section A	Have all Adverse Events and Special Situation Reports been received by the Safety Unit?	Yes ☐ No ☐ (if No, complete **Section B**) No Adverse Event(s)/Special Situation Report(s) reported ☐
Section B	Provide a list of Adverse Event(s)/Special Situation Report(s) not received by the Safety Unit	
	Date CTV form sender was contacted:	
	Date Adverse Event(s)/Special Situation Report(s) were received by the Safety Unit	
	Details of action taken in addition to avoid any future issues, if applicable	