Document No. PVPI_SPV.19.01_A01 **Version** 7.0	The collection, storage, processing and worldwide reporting of personal data connected to adverse events is required by international drug safety regulations. During this process, personal data is protected in accordance to the General Data Protection Regulations GDPR, REGULATION (EU) 2016/679 or other international legislation. As an additional precaution, certain personal data is made anonymous in, or withheld from, individual reports of safety data.
Title:	**GE Healthcare Pharmaceutical Diagnostics Adverse Event Intake Form**

Section to be completed by the Local Safety Unit (PV team) only		
	Receipt Date (LSU or LSU Representative's Awareness Date - *DD-MMM-YYYY format)*:	
	Local Case Number	
	Local Safety Unit (LSU) - Territory/Company name	

Reset Form [Clears entire form]

PART 1. REPORTER CONTACT INFORMATION

Reporter and Institution Name	Street Address	City	State/Country	Telephone /Fax	Email

Reporter type: ☐ Physician ☐ Pharmacist ☐ Other Healthcare Professional (HCP) ☐ Consumer/Other Non-HCP ☐ Lawyer ☐ Other:

PART 2. PATIENT INFORMATION

Patient Initials	Gender	Pregnant	Race / Ethnicity	Weight	Height	DOB *DD-MMM-YYYY*	Age (in years) or Age Group *(only complete if Year of Birth is unavailable)*
				☐kg ☐lb	☐cm ☐in		☐Neonate ☐Infant ☐Child ☐Adult ☐Elderly ☐Unknown

PART 3. ADVERSE EVENT INFORMATION (enter diagnosis and symptoms) / PRODUCT COMPLAINT INFORMATION

Adverse Event *(Provide diagnosis and/or symptom if available)*	Seriousness Criteria Event Outcome	Relationship Between AE and Suspect Drug	Time from Last Admin to Onset (latency)	Onset Date and Time *(DD-MMM-YYYY HH:MM AM/PM)*	Event End Date and Time *(DD-MMM-YYYY HH:MM AM/PM)*

PART 4. SUSPECT DRUG INFORMATION

Product Info	Batch No. / Lot No.	Exp.Date	Exam Type/ Procedure	Indication for procedure *(if known)*	Start Date and Time	Stop Date and Time	Dose (Units) & Frequency	Route	Formulation
Trade or Generic Name: Prev. Exp: ☐ Y ☐ N Tolerance: ☐ Y ☐ N						☐ ongoing			
Trade or Generic Name: Prev. Exp: ☐ Y ☐ N Tolerance: ☐ Y ☐ N						☐ ongoing			

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PART 5. ADDITIONAL DETAILS OF THE ADVERSE EVENT *(Include all available details about clinical course and any other details not specified in other fields. Include treatment for AE, if applicable. For treatment medication, include indication, start and stop dates, and route. For non-interventional studies, include Study ID, Patient ID, and Center or Site ID.)*

PART 6. CONCOMITANT MEDICATION INFORMATION (Include prescription, over-the-counter, and herbal medications)

Trade name or Generic name	Indication	Start date	Stop Date *(enter "ongoing" if no stop date)*	Dose (Units) & Frequency	Route

PART 7. RELEVANT MEDICAL CONDITIONS / HISTORY

Condition *(if information does not fit, add to 'Additional Details of the AE' section)*	Medical History (MH) OR Current Condition (CC)	Start Date	Stop Date
	☐ MH ☐ CC		
	☐ MH ☐ CC		
	☐ MH ☐ CC		
	☐ MH ☐ CC		

PART 8. SPECIFIED RISK FACTORS

	Risk Factor?	Start Date	Stop date	Specify allergy/ Comments
Allergies	☐ Y ☐ N ☐ Unk			
Asthma	☐ Y ☐ N ☐ Unk			
Dehydration	☐ Y ☐ N ☐ Unk			
Renal Impairment	☐ Y ☐ N ☐ Unk			

PART 9. RELEVANT DIAGNOSTIC TESTS (INCLUDING VITAL SIGNS)

Test name	Date	Results *(include units)*	Lab normal values *(include units)*

NAME	SIGNATURE	DATE

Please send completed form to the Central Safety Unit (CSU) at gpv.drugsafety@ge.com

Drop-down Menu QuickReference

Gender	Pregnant	Race / Ethnicity	Seriousness Criteria
• Male • Female • Other • Unknown	• Yes • No • Unknown	• Caucasian • Black • Asian • Other • African American • American Indian • Alaska Native • Native Hawaiian • Other Pacific Islander • White • Hispanic • Unknown	• Death • Life-threatening • Hospitalization • Prolonged Hospitalization • Disability • Congenital Anomaly • Important Medical Event • Non-serious • Unknown

Outcome	Relationship to Suspect Product	Formulation
• Recovered • Recovering • Not Recovered • Recovered with Sequelae • Death • Unknown	• Not Related • Not Reported • Related	• Solution for Injection • Solution for injection via pre-filled syringe • Oral Solution • Other (specify in Part 5) • Unknown

Date Format Quick Reference

dd-Mmm-yyyy

Receipt Date LSU or LSUs Representative's awareness date