SANOFI

Individual Safety Information Collection & Documentation form

Complete all available information and submit to Sanofi Pharmacovigilance (PV)

Person Completing This Form

Name, Title: Telephone:

Services Provider Name:

Program / Project Name or Number (if applicable):

Date Event was First Reported to Services Provider:

Patient Information (complete any known information):

Patient First Name/Initial: Patient Last Name:

Sex:

Unique Patient Identifier:

Date of Birth: Age:

Suspect Product Information (complete any known information)

Suspect Product Name:

Dose/Unit: Frequency: Route:

Therapy start date*:* Therapy stop date*:*

Ongoing: Indication:

Adverse Event Information (complete any known information)

Date adverse event started*:*

Describe event, corrective treatment, patient's medical history and concomitant treatment, if any: (provide start and end dates for each of the adverse events listed below). Please provide Batch Number for the Suspect Product (enter "Batch Number not available" if unable to obtain. Please indicate if the reporter requests not to be contacted for pharmacovigilance follow-up.):

Outcome of Event: **Related to Company Product:**

If fatal outcome:

Date of death:

Cause of death:

Treating Physician Information:

Name: Address:

Phone: Email:

Reporter Information (Who told you about this adverse event?)

Name: Address:

Healthcare Professional?

Phone: Email: