EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2026
EMA/11141/2026
European Medicines Agency

EU implementation strategy of ICH E2D(R1) Guideline - Post-approval safety data: Definitions and standards for management and reporting of individual case safety reports

Adopted by PRAC	20 February 2026

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

1. Introduction

The purpose of this document is to provide instructions on the practical implementation of the ICH E2D(R1) Guideline - Post-approval safety data: definitions and standards for management and reporting of individual case safety reports (EMA/CHMP/ICH/59123/2024) in the European Union (EU). It is intended to provide guidance for Marketing Authorisation Holders (MAHs), as well as for National Competent Authorities and Inspectors.

2. Implementation of ICH E2D(R1) in the EU

The revision of the ICH E2D guideline aims to clarify the management of safety data derived from solicited sources such as social media, market research programs, patient support programs, and others, which may differ in their characteristics and contributions to the quality of post-approval safety information. This revision provides also some updates on the definitions, standards, and regulatory guidance for the management and reporting of post-approval drug safety information with the objective of supporting appropriate safety surveillance of medicinal products in line with current practices and needs.

The revised Guideline ICH E2D(R1) has been adopted by the ICH Management committee and by the CHMP in September 2025 and it will come officially into effect in the EU 6 months later, on **18 March 2026**. As part of the PRAC Work Plan activities for 2026, the revision of the Good Pharmacovigilance Practice (GVP) Module VI will be initiated to integrate the updated ICH E2D(R1) Guideline. In the interim, the guidance and definitions set out in the revised guideline should be applied in accordance with this EU implementation strategy document. As a reminder, where ICH-E2D(R1) makes refence to regional or local requirements, GVP Module VI constitutes these requirements for the EU and the guidance provided in the current version should be followed as applicable.

In order to allow MAHs to update their processes accordingly, an additional 6-month transition period is permitted up to **18 September 2026**. After this date, the definitions and guidance provided in the ICH E2D(R1) Guideline will become applicable.

Further clarification is provided hereafter to support the implementation of the definition for Patient Support Programs (PSPs) and of the new documentation required for Organised Data Collection Systems (ODCSs) not conducted according to a protocol.

It should be noted that the implementation of the ICH E2D(R1) guideline in the EU is independent of the transition to the new ICH E2B(R3) values introduced in the data element C.5.4 'Study Type Where Reaction(s)/ Event(s) Were Observed' (i.e., PSP, Market Research Program (MRP), Organised Data Collection System (ODCS) with source data from digital platform). The implementation in the EU of these new values will be addressed separately at a later stage through the change management process for the EudraVigilance system.

3. Implementation of the definition for Patient Support Program

The following definition for PSP is introduced in the ICH E2D(R1) Guideline Chapter 2.9:

- *'PSPs are ODCSs initiated by an MAH, in which patients enrol for the purpose of supporting their use of the MAH's medicinal product, or the management of their medical condition, and which include a mechanism for two-way communication between the MAH (or third party acting on the MAH's behalf) and patients or healthcare professionals. Examples of PSPs include adherence*

support, disease management, and certain reimbursement and educational programs. See Section 4.5 Sources of ICSRs, PSPs, for further details.
Programs meet the definition of a PSP if 1) they solicit medical information about the patient's use of a medicinal product and/or 2) the design of the program is such that the MAH (or a third party acting on the MAH's behalf) would foreseeably receive medical information about the patient's use of a medicinal product (e.g., when a program involves HCP interaction with a patient to administer medication or provide medical advice).
MAH-initiated programs that do not meet the criteria above (e.g., delivery of a product to a patient's home, provision of vouchers or coupons) are not considered to be PSPs, as long as the MAH does not request medical information about the patient's use of a medicinal product. PSPs exclude: clinical trials; non-interventional studies, such as post-authorisation safety studies which have a scientific intent or are testing a hypothesis; all forms of compassionate use; and named patient supply.'

In addition, the guidance provided in ICH E2D(R1) Guideline Chapter 4.5 clarifies that if an Adverse Drug Reaction (ADR) from a PSP meets reporting requirements, it should be managed as solicited report, which includes an appropriate causality assessment. However, ADRs arising from MAH activities that only allow one-way interactions (e.g., delivery services, provision of vouchers or coupons) which are not part of an ODCS should be managed as spontaneous reports. Such standalone activities, which are not part of a combined multi-activity PSP, do not meet criteria for a PSP (i.e., do not have a mechanism for two-way interactions).

Currently, based on the EU guidance detailed in GVP Module VI Chapter VI.C.2.2.11, all ADRs from PSPs should be managed as solicited without making distinction on the program design. The new definition and guidance for PSP detailed in ICH E2D(R1) Guideline Chapters 2.9 and 4.5 excludes certain types of programs which historically may have been considered to be PSPs (e.g., MAH activities that only allow one-way interactions such as delivery of a product to a patient's home, or provision of vouchers or coupons), and ADRs from such programs should be managed as spontaneous reports rather than solicited.

In line with the requirements provided in GVP Module VI Chapter VI.C.2.2 regarding the responsibilities of the MAH in the EU, the following implementation strategy should be followed for program activities conducted within or outside the EU:

a. The new definition introduced in the ICH E2D(R1) Guideline Chapter 2.9 for PSP should be implemented by MAHs **no later than 18 September 2026 for all new programs**. The ADRs arising from these activities should be managed according to the guidance provided in ICH E2D(R1) Guideline Chapter 4.5, i.e., as solicited for ADRs from PSPs, and as spontaneous for ADRs from MAH activities that only allow one-way interactions (e.g. delivery services, provision of vouchers or coupons) which are not part of an ODCS, or which are not part of a combined multi-activity PSP.

   Based on the guidance provided in GVP Module VI Chapter VI.6.2.3.7 Subsection 1, the value '3 = Other studies (e.g., pharmacoepidemiology, pharmacoeconomics, intensive monitoring)' should continue to be used in data element C.5.4 'Study Type Where Reaction(s) / Event(s) Were Observed' for ICSRs originating from PSPs, until the new value '4 = Patient Support Program' is implemented in EudraVigilance at a later stage (see chapter 2 of this implementation strategy document). For ADRs arising from MAH activities that only allow one-way interactions, data element C.1.3 'Type of report' should be populated with the value '1= Spontaneous report'.

b. For **ongoing programs started before 18 September 2026**, the new definition provided in the ICH E2D(R1) Guideline Chapter 2.9 can be implemented by MAHs on a voluntary basis. The management of ADRs from MAH activities that only allow one-way interactions (e.g. delivery services, provision of vouchers or coupons), which are not part of an ODCS, or which are not part of a combined multi-activity PSP, can be changed from solicited to spontaneous providing that this is clearly documented by the MAH in the new detailed documentation required for ODCSs not conducted according to a protocol (see chapter 4 below). Once the switch is implemented, all new and follow-up ADRs received from the concerned program should be managed as spontaneous.

4. Implementation of the detailed documentations required for Organised Data Collection Systems not conducted according to a protocol

As provided in the ICH E2D(R1) Guideline Chapter 2.8, the following definition is introduced for ODCSs:

- *'For the purposes of this document, an organised data collection system (ODCS) is an activity that gathers data relevant to an MAH's medicinal product or a medical disease area, in a planned manner, thereby enabling review to be performed.*
  Regional or local regulatory authorities may require a protocol for certain types of ODCS (i.e., clinical trials and non-interventional studies). In this context a protocol means a document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial or study. The term 'protocol' encompasses successive versions of the protocol and protocol modifications.
  For MAH ODCS activities that are not conducted according to a protocol (e.g., a market research program, a patient support program, or accessing data on a digital platform in the context of an ODCS), the MAH should have documentation in place that at least describes the:

  1. *Objectives of the ODCS activity;*
  2. *Source(s) of the data;*
  3. *Dataset that the MAH will collect or receive and review in order to meet the objectives of the activity detailed under item 1, including the look-back period and/or duration of the data collection;*
  4. *Method the MAH will use to review the dataset to meet the objective of the activity;*
  5. *Process for collection and management of any AEs/ADRs or other observations that may be identified.*

  For the purposes of this Guideline, ODCS excludes the MAHs' standard procedures for the surveillance, receipt, evaluation, and reporting of spontaneous postmarketing ADRs and other postmarketing ADRs managed as spontaneous reports (i.e., the MAHs' routine pharmacovigilance operations for spontaneous reports), see Section 4, Sources of ICSRs.
  Specific examples of ODCS in the context of this Guideline include clinical trials, non-interventional studies (e.g., pharmacoepidemiologic, drug utilisation studies, registries), patient support programs, and market research programs. Other examples include: an MAH activity using a patient forum on a digital platform to assess patient perceptions of the safety of disease treatments; and a product-specific analysis of consumer positivity or negativity about the product (i.e., a sentiment analysis) conducted by an MAH using posts on social media networking sites. In addition, an activity where an MAH monitors and analyzes user communications on a social media site, often referred to as social listening or digital listening, is an example of an ODCS.'

In the EU, ODCSs are currently described in GVP Module VI Chapter VI.B.1.2 within the definition of solicited reports. The definition in the ICH E2D(R1) Guideline Chapter 2.8 introduces the new provision for the MAH to have a documentation in place when the MAH ODCS activities are not conducted according to a protocol.

In line with the requirements provided in GVP Module VI Chapter VI.C.2.2 regarding the responsibilities of the MAH in the EU, the following implementation strategy for the new required documentation should be followed by MAHs for ODCS conducted within or outside the EU:

a. **Each new MAH ODCS activity** not conducted according to a protocol should have the ICH E2D(R1) documentation in place no later than **18 September 2026** describing at least the:

    1. Objectives of the ODCS activity;
    2. Source(s) of the data;
    3. Dataset that the MAH will collect or receive and review in order to meet the objectives of the activity detailed under item 1, including the look-back period and/or duration of the data collection;
    4. Method the MAH will use to review the dataset to meet the objective of the activity;
    5. Process for collection and management of any AEs/ADRs or other observations that may be identified.

    The documentation should be maintained with oversight by the Qualified Person responsible for Pharmacovigilance (QPPV) and made available to the national competent authorities and the Agency upon request.

b. **Each ongoing MAH ODCS activity** not conducted according to a protocol should have the ICH E2D(R1) documentation in place no later than **18 September 2026** describing at least the:

    1. Objectives of the ODCS activity;
    2. Source(s) of the data;
    3. Process for collection and management of any AEs/ADRs or other observations that may be identified.

    The documentation should be maintained with oversight by the QPPV and made available to the national competent authorities and the Agency upon request.