ICH
harmonisation for better health

ICH E2D(R1) Post Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports (ICSRs)

Training material

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International Council for Harmonisation of Technical Requirements
for Pharmaceuticals for Human Use

Legal Notice

Abbreviations

- AE: Adverse Event
- ADR: Adverse Drug Reaction
- HCP: Healthcare Professional
- ICSR: Individual Case Safety Report
- MAH: Marketing Authorisation Holder
- MRP: Market Research Program
- ODCS: Organised Data Collection System
- PSP: Patient Support Program

Background

- This material has been developed to support implementation of the ICH E2D(R1) Guideline.
- ICH E2D(R1) establishes a framework for current best practices of post-approval safety data management in a dynamic environment.
- Practical examples in this material illustrate the concepts used in ICH E2D(R1) and in planned updates to ICH E2B(R3) coding practices.
  - To support stratification of cases by their source during signal detection and signal analysis, three new values will be added to ICH E2B(R3) data element C.5.4, 'Study Type Where Reaction(s)/Event(s) Were Observed'.

Background (continued)

- ICH E2B(R3) EWG/IWG has published the updates shown in red in an ICH E2B(R3) Information Paper, to be followed by updates to the ICH E2B(R3) Implementation Guide.

Type of Report ICH E2B(R3) C.1.3	**Study Type Where Reaction(s) / Event(s) Were Observed** ICH E2B(R3) C.5.4 (only populated if Type of Report = 2, (ICH E2B(R3) C.1.3)) *
1 = Spontaneous report 2 = Report from study * 3 = Other 4 = Not available to sender (unknown)	1 = Clinical trials 2 = Individual patient use(e.g. 'compassionate use' or 'named patient basis') 3 = Other studies (e.g. pharmacoepidemiology, pharmacoeconomics, intensive monitoring) *4 = Patient Support Programme* *5 = Market Research Programme* *6 = Organised Data Collection System with source data from a digital platform*

*** V0 '2=report from study' and the data element 'study type where reaction(s)/event(s) were observed' is used for studies as well as other Organised Data Collection Systems**

Key Concepts

- Key ICH E2D(R1) concepts covered by the examples include:

Concept	Example
Distinction between spontaneous and solicited sources	1-13, 15, 17-23
Spontaneous reports on digital platforms under MAH responsibility	1-4
Reports from literature	
Study report from literature	5
Spontaneous report from literature	6
Reports from a Non-MAH registry on a digital platform	7
PSP with in-person communication with patients	8
PSP using a mobile app	9
Documentation needed for Organized Data Collection Systems (ODCSs)	10

Key Concepts (continued)

- Key ICH E2D(R1) concepts covered by the examples include:

Concept	Example
Designating programs as PSP or not	
Re-imbursement program without two-way communication	11
Re-imbursement program with direct patient contact and collection of medical information	12
Delivery service	13
Educational program on a website with one-way communication	14
Combined program with delivery service and direct patient contact	15
Medication adherence program sending automated reminders	16
Patient Assistance Program with ability for HCPs to upload medical records	17

Key Concepts (continued)

- Key ICH E2D(R1) concepts covered by the examples include:

Concept	Example
Report of Outcome (e.g., death) only	13
Market Research Program	
In-person communication with Health Care Professionals (HCPs) and patients	18
MRP on a digital platform	19
MAH accesses data on a digital platform not under its responsibility	
MAH conducts a planned 'social listening' activity	20
MAH employee views social media platform outside the context of an ODCS	21
MAH accesses data on a digital platform as part an ODCS	22
MAH contractual agreement with a social media influencer	23

Example 1

A patient experiences an AE/ADR. The patient accesses the Market Authorisation Holder's (MAH's) product information website and uses a webform to report an AE/ADR to the MAH.

- In this example, the MAH is receiving information about an Adverse Event/Adverse Drug Reaction (AE/ADR) on a Digital Platform (DP) under their responsibility.
- MAHs should regularly screen digital platforms under their responsibility for AEs/ADRs.
- The context in which the MAH received the AE/ADR (regardless of the route (e.g., via webform, chat box, email or other digital platform)) is relevant to determine whether the case should be managed as spontaneous or solicited (i.e., Type of report: '1=Spontaneous or 2=Report from study').

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Example 1 (continued)

A patient experiences an AE/ADR. The patient accesses the MAH's product information website and uses a webform to report an AE/ADR to the MAH.

- See ICH *E2D(R1) Section 4.3.1, Digital Platforms Under the Responsibility of the MAH*:

"AEs/ADRs should be managed as spontaneous or solicited depending on the context in which the MAH received the report: for example, AEs/ADRs spontaneously reported by patients on any part of an MAH's product website should be managed as spontaneous reports (see Section 3.1 Spontaneous Reports)."

- In this example, the patient is reporting the AE/ADR on their own initiative (i.e., it was not gathered as part of an organized Data Collection System (ODCS)) via the MAH's website. Thus, this AE/ADR should be managed as a spontaneous report.
- See also *ICH E2D(R1) Section 6.1, Assessing Patient and Reporter Identifiability*, which provides guidance on the reporter and patient identifiability for cases from digital platforms.

E2B(R3) values

Type of report: '*1=Spontaneous*'
Study type: not applicable

Example 2

An MAH operates a disease awareness website. A patient reports an AE/ADR on their own initiative via the website.

- In this example, the MAH is receiving information about an AE/ADR on a Digital Platform under their responsibility.
- MAHs should regularly screen digital platforms under their responsibility for AEs/ADRs.
- The context in which the MAH received the AE/ADR (regardless of the route (e.g., via webform, chat box, email or other digital platform)) is relevant to determine whether the case should be managed as spontaneous or solicited (i.e., Type of Report: '1=Spontaneous' or '2=Report from study').
- See ICH *E2D(R1) Section 4.3.1, Digital Platforms Under the Responsibility of the MAH*:

  "AEs/ADRs should be managed as spontaneous or solicited depending on the context in which the MAH received the report: for example, AEs/ADRs spontaneously reported by patients on any part of an MAH's product website should be managed as spontaneous reports (see Section 3.1 Spontaneous Reports)."

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Example 2 (continued)

An MAH operates a disease awareness website. A patient reports an AE/ADR on their own initiative via the website.

- In this example, the patient is reporting the AE/ADR on their own initiative via the MAH's website. Thus, this AE/ADR should be managed as a spontaneous report.
- See also *ICH E2D(R1) Section 6.1, Assessing Patient and Reporter Identifiability*, which provides guidance on the reporter and patient identifiability for cases from digital platforms.

E2B(R3) values

Type of report: '*1=Spontaneous*'
Study type: not applicable

Example 3

An MAH established a Facebook page where they communicate various content about one of their medical products. The content on the page is controlled by the MAH.
A patient leaves a comment describing an AE/ADR.

- In this example, the MAH is receiving information about an AE/ADR on a Digital Platform under their responsibility.
- See ICH *E2D(R1) Section 4.3.1, Digital Platforms Under the Responsibility of the MAH*:

  "The MAH is responsible for the content of, and communications made available via digital platforms, that are owned, controlled, or operated by, or on behalf of, the MAH."

- MAHs should regularly screen digital platforms under their responsibility for AEs/ADRs.
- The context in which the MAH received the AE/ADR (regardless of the route (e.g., via webform, chat box, email or other digital platform)) is relevant to determine whether the case should be managed as spontaneous or solicited (i.e., Type of Report: '1=Spontaneous' or '2=Report from study').

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Example 3 (continued)

An MAH established a Facebook page where they communicate various content about one of their medical products. The content on the page is controlled by the MAH.
A patient leaves a comment describing an AE/ADR.

- See ICH *E2D(R1) Section 4.3.1, Digital Platforms Under the Responsibility of the MAH*:

  "AEs/ADRs should be managed as spontaneous or solicited depending on the context in which the MAH received the report: for example, AEs/ADRs spontaneously reported by patients on any part of an MAH's product website should be managed as spontaneous reports (see Section 3.1 Spontaneous Reports)."

- In this example, the patient is reporting the AE/ADR on their own initiative on a digital platform under the MAH's responsibility (company's Facebook page). The AE/ADR should be managed as a spontaneous report.

- See also *ICH E2D(R1) Section 6.1, Assessing Patient and Reporter Identifiability*, which provides guidance on the reporter and patient identifiability for cases from digital platforms.

E2B(R3) values

Type of report: '*1=Spontaneous*'
Study type: not applicable

Example 4

An MAH receives information about an AE/ADR for one of its products through a company's corporate website that is not related to the company's products or diseases (e.g., a page posting employment opportunities with the company or a page discussing the company's financial performance).

- MAHs should regularly screen digital platforms under their responsibility for AEs/ADRs.
- See ICH *E2D(R1) Section 4.3.1, Digital Platforms Under the Responsibility of the MAH*:

  "The MAH is responsible for the content of, and communications made available via digital platforms, that are owned, controlled, or operated by, or on behalf of, the MAH."

- See also *ICH E2D(R1) Section 6.1, Assessing Patient and Reporter Identifiability*, which provides guidance on the reporter and patient identifiability for cases from digital platforms.

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Example 4 (continued)

An MAH receives information about an AE/ADR for one of its products through a company's corporate website that is not related to the company's products or diseases (e.g., a page posting employment opportunities with the company or a page discussing the company's financial performance).

- In this example, the MAH is receiving information about an AE/ADR on a digital platform under the MAH's responsibility (company's corporate website) which is not gathered as part of an ODCS.
- So, it should be managed as a spontaneous report.

E2B(R3) values

Type of report: '*1=Spontaneous*'
Study type: not applicable

Example 5

A literature article describes an AE/ADR that originates from a non-interventional study (not conducted by the MAH).

- Whether or not AEs/ADRs from literature are required to be reported as ICSRs depends on regional and local requirements (see *ICH E2D(R1) Section 4.2, Literature*).
- In this example, if the MAH determines that an ICSR meets reporting requirements, the ICSR should be managed as a solicited report, and the value '3=Other studies (e.g., pharmaco-epidemiology, pharmacoeconomics, intensive monitoring)' should be selected as the 'Study Type'.

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Example 5 (continued)

A literature article describes an AE/ADR that originates from a non-interventional study (not conducted by the MAH).

- See *ICH E2D(R1) Section 4.2, Literature*:

"if a case in the literature arises from a study, "Type of Report" in ICH E2B(R3) format should be classified as "report from study". Literature cases arising from a study are AEs/ADRs identified from publications where the author(s) gathered the cases only as part of an ODCS (for example, an author who plans and conducts a search of a dataset for cases meeting pre-specified criteria); see Section 2.8, Organized Data Collection System."

E2B(R3) values

Type of report: '*2=Report from study'*
Study Type: = *'3=Other studies (e.g., pharmaco-epidemiology, pharmacoeconomics, intensive monitoring)'*

Example 6

A cardiologist evaluates and treats two male teenagers who experienced myocarditis less than 7 days after receiving a COVID-19 vaccination. The cardiologist publishes a case report about the teens' cases.

- Whether or not AEs/ADRs from literature are required to be reported as ICSRs depends on regional and local requirements (see *E2D(R1) Section 4.2, Literature*).
- If a determination is made by the MAH to submit the ICSR, then it should be managed as a spontaneous report.
- See *ICH E2D(R1) Section 4.2, Literature*:

"If a case in the literature arises from spontaneous observations, "Type of Report" in ICH E2B(R3) format should be classified as "spontaneous report". In this context, spontaneous observations are descriptions of AEs/ADRs in a patient or group of patients (i.e., individual case report or case series) which the author(s) identified in their clinical experience."

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Example 6 (continued)

A cardiologist evaluates and treats two male teenagers who experienced myocarditis less than 7 days after receiving a COVID-19 vaccination. The cardiologist publishes a case report about the teens' cases.

- In this example, the author of the literature article described two cases that the author encountered in their clinical experience, so these cases should be considered spontaneous reports. The MAH should submit an ICSR for each case; see ICH E2D(R1), Section 4.2, Literature:

"When submitting ICSRs from literature, an ICSR with relevant medical information should be provided for each identifiable patient (see Section 6.1, Assessing Patient and Reporter Identifiability)."

E2B(R3) values

Type of report: '*1=Spontaneous*'
Study type: not applicable

Example 7

A non-commercial organisation that focuses on a medical disease area operates a pregnancy registry and makes data available on their website. Via this website the MAH becomes aware of an AE/ADR that is recorded in the registry.

- The registry is an organized data collection system (ODCS) conducted by the non-commercial organization, not the MAH (see *ICH E2D(R1) Section 2.8, Organised Data Collection System*).
- In this example, if the AE/ADR meets reporting requirements, it should be managed as solicited, because the AE/ADR was originally gathered in the context of an ODCS (i.e., the registry study); the value '3=Other studies (e.g., pharmaco-epidemiology, pharmacoeconomics, intensive monitoring)' should be selected as the 'Study Type' to reflect the registry as a pharmacoepidemiology study (see *E2D(R1) Sections 3.2, Solicited Reports and 5.1.1, AEs/ADRs*).

E2B(R3) values

Type of report: '*2=Report from study*'
Study Type: *'3=Other studies (e.g., pharmaco-epidemiology, pharmacoeconomics, intensive monitoring)'*

Example 8

A nurse visits a patient in the context of a Patient Support Program (PSP) to administer a medicine. The patient tells the nurse about a suspected AE/ADR.

- MAHs should review all information received in a PSP for AEs/ADRs.
- AEs/ADRs that the MAH becomes aware of in the context of a PSP should be recorded, managed and assessed for reporting as required by regional or local requirements.
- In this example, if the AE/ADR from a PSP meets reporting requirements, it should be managed as a solicited report (see *ICH E2D(R1) Section 4.5, Patient Support Programs*) and the value 4 = 'Patient Support Program' should be selected.

E2B(R3) values

Type of report: '*2=Report from study*'
Study type: '*4=Patient Support Program*'

Example 9

An MAH operates a Patient Support Program (PSP) where a mobile app is used to keep in touch with patients. While an MAH representative is communicating via the app with one of the patients in the PSP, the patient describes an AE/ADR.

- MAHs should review all information received in a PSP for AEs/ADRs.
- AEs/ADRs that the MAH becomes aware of in the context of a PSP should be recorded, managed and assessed for reporting as required by regional or local requirements.
- In this example, if the AE/ADR from a PSP meets reporting requirements, it should be managed as a solicited report (see *Section 4.5, Patient Support Programs*).

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Example 9 (continued)

An MAH operates a Patient Support Program (PSP) where a mobile app is used to keep in touch with patients. While an MAH representative is communicating via the app with one of the patients in the PSP, the patient describes an AE/ADR.

- The value '4=*Patient Support Program*' should be selected.
- Note: The value '6=Organised Data Collection System with source data from a digital platform' should only be used for the 'Study Type Where reaction(s)/event(s) Were Observed' data element if the AE/ADR was collected from a digital platform and none of the other study types apply.

E2B(R3) values

Type of report: '*2=Report from study*'
Study type: '*4=Patient Support Program*'

Example 10

An MAH is conducting a Market Research Program (MRP) for a business-related purpose (i.e., the objective of the program is not related to collecting safety information).

The MAH does not need a protocol to conduct the MRP and is working on creating documentation of the program objectives, timeline and the handling and management of AEs/ADRs.

- Section 2.8 of ICH E2D(R1) includes the minimum required documentation that MAHs should have in place for MAH organized data collection system (ODCS) activities that are not conducted according to a protocol (e.g., an MRP, a patient support program (PSP), or accessing data on a digital platform in the context of an ODCS).

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Example 10 (continued)

An MAH is conducting a Market Research Program (MRP) for a business-related purpose (i.e., the objective of the program is not related to collecting safety information).

The MAH does not need a protocol to conduct the MRP and is working on creating documentation of the program objectives, timeline and the handling and management of AEs/ADRs.

- In this example, MAHs "should have documentation in place that at least describes:

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 lookback 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 (see ICH E2D(R1) Section 2.8, ODCS)."

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Example 10 (Continued)

An MAH is conducting a Market Research Program (MRP) for a business-related purpose (i.e., the objective of the program is not related to collecting safety information).

The MAH does not need a protocol to conduct the MRP and is working on creating documentation of the program objectives, timeline and the handling and management of AEs/ADRs.

- Regardless of the MAH's purpose or objectives of the program, the MAH should review all information received in an MRP or PSP for AEs/ADRs.
- See *ICH E2D(R1) Sections 4.5 Patient Support Programs* and *4.6 Market Research Programs*:

"AEs/ADRs that the MAH becomes aware of in the context of a PSP [or MRP] should be recorded, managed and assessed for reporting as required by regional or local requirements.… If an AE/ADR from a PSP [or MRP] meets reporting requirements, it should be managed as a solicited report which includes an appropriate causality assessment (see Section 5.1.1, AEs/ADRs)."

E2B(R3) values

Type of report: '*2=Report from study*'
Study type: '5= *Market Research Program*'

Example 11

A patient is enrolled in an MAH's financial support (re-imbursement) program that does not include a mechanism for two-way communication between the MAH and program participants.

The patient contacts the MAH via the MAH's regular consumer service line and reports an AE/ADR.

- When developing programs for patients, the MAH should consider the designation of the program as a Patient Support Program (PSP) or not.
- To determine if a program meets the definition of a PSP, see *ICH E2D(R1) Section 2.9, Patient Support Program*.
- In this example, the MAH's re-imbursement program is not considered to be a PSP, because the program does not include a mechanism for two-way communication between the MAH and the patients.
- The AE/ADR in this case should be handled as a spontaneous report.

E2B(R3) values

Type of report: '*1=Spontaneous*'
Study type: not applicable

Example 12

A patient contacts a MAH, or a third party (e.g., vendor) operating on the MAH's behalf, in the context of a financial support (re-imbursement) program and describes an AE/ADR.

The program supports the patient via face-to-face, phone or online interactions collecting necessary medical information for managing the program.

- When developing programs for patients, the MAH should consider the designation of the program as a Patient Support Program (PSP) or not.
- To determine if a program meets the definition of a PSP, see *ICH E2D(R1) Section 2.9, Patient Support Program*.
- In this example, the MAH program is considered to be a PSP, because the program includes a two-way mechanism for communication between the MAH and patients, and it is designed such that the MAH would foreseeably receive medical information about the patient's use of a medicinal product.

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Example 12 (continued)

A patient contacts a MAH, or a third party (e.g., vendor) operating on the MAH's behalf, in the context of a financial support (re-imbursement) program and describes an AE/ADR.

The program supports the patient via face-to-face, phone or online interactions collecting necessary medical information for managing the program.

- MAHs should review all information received in a PSP for AEs/ADRs.
- AEs/ADRs that the MAH becomes aware of in the context of a PSP should be recorded, managed and assessed for reporting as required by regional or local requirements.
- If an AE/ADR from a PSP meets reporting requirements, it should be managed as a solicited report, and the value '4=Patient Support Program' should be selected as the 'Study Type' (see *ICH E2D(R1) Section 4.5, Patient Support Programs*).

E2B(R3) values

Type of report: *'2=Report from study'*
Study type: '4=*Patient Support Program'*

Example 13

A patient is enrolled in a program consisting of the delivery of a medicinal product by a third-party service provider.

The service provider contacts the patient to arrange delivery of the product and is informed that the patient has died.

- When developing programs for patients, the MAH should consider the designation of the program as a Patient Support Program (PSP) or not.
- To determine if a program meets the definition of a PSP, see *ICH E2D(R1) Section 2.9, Patient Support Program*.
- In this example, the MAH program is not considered to be a PSP and is also not part of an Organised Data Collection System (ODCS).

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Example 13 (continued)

A patient is enrolled in a program consisting of the delivery of a medicinal product by a third-party service provider.

The service provider contacts the patient to arrange delivery of the product and is informed that the patient has died.

- AEs/ADRs arising from MAH activities that only allow one-way interactions (e.g., delivery services, provision of vouchers or coupons) 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) (see *ICH E2D(R1) Section 4.5, Patient Support Programs*).
- Note that cases that contain only an outcome (e.g., death) should only be reported as an ICSR if required by regional or local requirements (see *ICH E2D(R1), Section 5.1.1 AEs/ADRs*).

E2B(R3) values

Type of report: '*1=Spontaneous*'
Study type: not applicable

Example 14

An MAH is considering whether their patient education program should be designated as a Patient Support Program (PSP).

The MAH operates the program over a website. The website is used to communicate educational information to patients about drug adherence.

Patients enroll in the program via the website, but no medical information is collected. There is no option for patients to share information with the MAH as "free text" entry on the website and there is no option for patients to upload or attach documents.

- When developing such programs the MAH should consider the designation of the program as a patient support program (PSP) or not.
- To determine if a program meets the definition of a PSP, see *ICH E2D(R1) Section 2.9, Patient Support Program*.

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Example 14 (continued)

An MAH is considering whether their patient education program should be designated as a Patient Support Program (PSP).

The MAH operates the program over a website. The website is used to communicate educational information to patients about drug adherence.

Patients enroll in the program via the website, but no medical information is collected. There is no option for patients to share information with the MAH as "free text" entry on the website and there is no option for patients to upload or attach documents.

- In this example, this program is not considered to be a PSP, because:
  - The MAH is not soliciting medical information and
  - It is not designed in such a way that the MAH would foreseeably receive medical information about the patient's use of the product (i.e., the educational information is communicated one-way only, and there is no mechanism for 2-way communication).

Example 15

A patient is enrolled in a program which combines the delivery of a medicinal product by a third-party service provider and the administration of the product by a nurse.

The service provider contacts the patient and is informed about an AE/ADR.

- When developing programs for patients, the MAH should consider the designation of the program as a Patient Support Program (PSP) or not.
- To determine if a program meets the definition of a PSP, see *ICH E2D(R1) Section 2.9, Patient Support Program*.

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Example 15 (continued)

A patient is enrolled in a program which combines the delivery of a medicinal product by a third-party service provider and the administration of the product by a nurse.

The service provider contacts the patient and is informed about an AE/ADR.

- This example concerns a delivery service combined with another activity that meets criteria of a PSP (see *ICH E2D(R1) Section 4.5, Patient Support Programs*):

"A single PSP may include a combination of activities such as nurse support, chatrooms, and delivery services. Each of the individual activities in the combined program may or may not meet the criteria of a PSP (see Section 2.9, PSP) on its own.

For example, a stand-alone service delivering product to a patient's home would not meet the criteria for a PSP (see Section 2.9, PSP). However, if a program includes delivery service combined with another activity that does meet criteria of a PSP (such as a nurse helping to administer a drug), then the combined program is considered a PSP.

If any one or more of the individual activities in the combined program do meet the PSP criteria, then AEs/ADRs received from any part of the program should be managed as coming from a PSP (i.e., as solicited reports)."

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Example 15 (continued)

A patient is enrolled in a program which combines the delivery of a medicinal product by a third-party service provider and the administration of the product by a nurse.

The service provider contacts the patient and is informed about an AE/ADR.

- AEs/ADRs that the MAH becomes aware of in the context of a PSP should be recorded, managed and assessed for reporting as required by regional or local requirements.
- In this example, the AE/ADR is reported via a combined program; if the AE/ADR meets reporting requirements, it should be managed as a solicited report and the value '4=*Patient Support Program*' should be selected as the '*Study Type*'.

E2B(R3) values

Type of report: *'2=Report from study'*
Study type: '4=*Patient Support Program*'

Example 16

An MAH is considering whether their medication adherence program should be designated as a Patient Support Program (PSP).

The MAH operates a program which is designed to help participants with medication adherence. The program sends dosing reminders to patients at scheduled intervals via automated SMS text messages, automated pre-recorded telephone messages (i.e., “robo-calls”), emails, and physical reminder postcards.

These automated messages do not request information and do not allow for the recipients to send replies.

In the SMS text messages, the patient is prompted to reply only if he/she wants to opt-out of the program by texting a number or a single word such as "stop".

- When developing programs for patients, the MAH should consider the designation of the program as a Patient Support Program (PSP) or not.
- To determine if a program meets the definition of a PSP, see *ICH E2D(R1) Section 2.9, Patient Support Program*.

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Example 16 (continued)

An MAH is considering whether their medication adherence program should be designated as a Patient Support Program (PSP).

The MAH operates a program which is designed to help participants with medication adherence. The program sends dosing reminders to patients at scheduled intervals via automated SMS text messages, automated pre-recorded telephone messages (i.e., “robo-calls”), emails, and physical reminder postcards.

These automated messages do not request information and do not allow for the recipients to send replies.

In the SMS text messages the patient is prompted to reply only if he/she wants to opt-out of the program by texting a number or a single word such as "stop’".

- In this example, this program is not considered to be a PSP, because:
  - The MAH is not soliciting medical information and
  - It is not designed in such a way that the MAH would foreseeably receive medical information about the patient’s use of the product (i.e., the dosing reminders are communicated one-way only, and there is no mechanism for 2-way communication).

Example 17

An MAH is considering whether their Patient Assistance Program (PAP) should be designated as a Patient Support Program (PSP).

The MAH is conducting a PAP to help certain patients with the cost of their medicinal product. The MAH is executing the program over a web portal which provides the option for Health Care Professionals (HCPs) to upload medical records for review by the MAH to verify that the patient is eligible for financial assistance.

- When developing such programs the MAH should consider the designation of the program as a Patient Support Program (PSP) or not.
- To determine if a program meets the definition of a PSP, see *ICH E2D(R1) Section 2.9, Patient Support Program*.
- In this example, the MAH may receive patient medical records that Health Care Professionals (HCPs) upload via the web portal to verify the patient's eligibility for treatment. This program is considered to be a PSP, because the program is designed such that the MAH would foreseeably receive medical information about the patient's use of a medicinal product.

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Example 17 (continued)

An MAH is considering whether their Patient Assistance Program (PAP) should be designated as a Patient Support Program (PSP).

The MAH is conducting a PAP to help certain patients with the cost of their medicinal product. The MAH is executing the program over a web portal which provides the option for HCPs to upload medical records for review by the MAH to verify that the patient is eligible for financial assistance.

- MAHs should review all information received in a PSP for AEs/ADRs.
- AEs/ADRs that the MAH becomes aware of in the context of a PSP should be recorded, managed and assessed for reporting as required by regional or local requirements.
- If an AE/ADR from a PSP meets reporting requirements, it should be managed as a solicited report and the value '4= Patient Support Program' should be selected as the 'Study Type' (see *ICH E2D(R1) Section 4.5, Patient Support Programs*).

E2B(R3) values

Type of report: *'2=Report from study'*
Study type: '*4= Patient Support Program'*

Example 18

An MAH, or a third party (e.g., vendor) operating on the MAH's behalf, organises face to face interviews and focus groups to question HCPs and patients as part of marketing research on their new asthma medication.

During the interview a patient shares information about a suspected AE/ADR.

- Market research programs (MRPs) are organized data collection systems (ODCSs) used for the planned collection of healthcare professional and/or consumer insights by an MAH (or a third party acting on the MAH's behalf), on medicinal products and/or a disease area, for the purpose of marketing and business development (see *ICH E2D(R1) Section 2.10, Market Research Program*).
- MAHs should review all information received in an MRP for AEs/ADRs.

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Example 18 (continued)

An MAH or a third party (e.g., vendor) operating on the MAH's behalf organises face to face interviews and focus groups to question HCPs and patients as part of marketing research on their new asthma medication.

During the interview a patient shares information about a suspected AE/ADR.

- AEs/ADRs that the MAH becomes aware of in the context of an MRP should be recorded, managed and assessed for reporting as required by regional or local requirements.
- If an AE/ADR from an MRP meets reporting requirements, it should be managed as a solicited report (see *ICH E2D(R1) Section 4.6, Market Research Programs*).
- In this example, the AE/ADR was collected in the context of a MRP, and the value '5= Market Research Program' should be selected as the 'Study Type'.

E2B(R3) values

Type of report: *'2=Report from study'*
Study type: '5=Market Research Program'

Example 19

An MAH, or a third party (e.g., vendor) operating on the MAH's behalf, sets up a closed Facebook group to conduct market research on its heart disease drugs.

A patient shares information about a suspected AE/ADR via that platform.

- Market research programs (MRPs) are organized data collection systems (ODCSs) used for the planned collection of healthcare professional and/or consumer insights by an MAH (or a third party acting on the MAH's behalf), on medicinal products and/or a disease area, for the purpose of marketing and business development (see *ICH E2D(R1) Section 2.10, Market Research Program*).
- MAHs should review all information received in an MRP for AEs/ADRs.
- AEs/ADRs that the MAH becomes aware of in the context of an MRP should be recorded, managed and assessed for reporting as required by regional or local requirements.

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Example 19 (continued)

An MAH, or a third party (e.g., vendor) operating on the MAH's behalf, sets up a closed Facebook group to conduct market research on its heart disease drugs.

A patient shares information about a suspected AE/ADR via that platform.

- If an AE/ADR from an MRP meets reporting requirements, it should be managed as a solicited report (see *ICH E2D(R1) Section 4.6, Market Research Programs*).
- In this example, a market research activity is conducted by a MAH, or a third party (e.g., vendor), operating on the MAH's behalf, using a digital platform (the Facebook group).
- The AE/ADR is collected in the context of an MRP using a digital platform, and the value '5= Market Research Program' should be selected as the 'Study Type'.
- Note: The value '6=Organised Data Collection System with source data from a digital platform' should only be used as the 'Study Type' if the AE/ADR was collected from a digital platform and none of the other study types apply.

E2B(R3) values

Type of report: *'2=Report from study'*
Study type: '5=Market Research Program'

Example 20

An MAH conducts a planned 'social listening' activity in a 'chat forum' that is not under the responsibility of the MAH.

The MAH becomes aware of AE/ADRs.

- This activity is considered to be an ODCS, and the MAH should have documentation in place (see *ICH E2D(R1) Section 2.8, ODCS*).
- If an MAH screens or accesses data from a digital platform not under its responsibility, and the MAH's activity is conducted in a planned manner consistent with an organised data collection, the MAH should consider the activity to be an organized data collection system (ODCS).
  - The MAH is not expected to search for AEs/ADRs beyond conducting its planned review of the dataset collected for the activity as detailed in its documentation.
  - If the MAH identifies AEs/ADRs during the course of the review, the AEs/ADRs should be recorded, managed and assessed for reporting as required by regional or local requirements.

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Example 20 (continued)

An MAH conducts a planned 'social listening' activity in a 'chat forum' that is not under the responsibility of the MAH.

The MAH becomes aware of AE/ADRs.

- If an AE/ADR collected from a digital platform in the context of an ODCS meets reporting requirements, it should be managed as a solicited report, and the value '6=Organised Data Collection System with source data from a digital platform' should be selected as the 'Study Type' (see *E2D(R1) Section 4.3.2, Digital Platforms Not Under the Responsibility of the MAH).*
- See also *ICH E2D(R1) Section 6.1, Assessing Patient and Reporter Identifiability*, which provides guidance on the reporter and patient identifiability for cases from digital platforms.

E2B(R3) values

Type of report: *'2=Report from study'*
Study type: '6=*Organised Data Collection System with source data from a digital platform'*

Example 21

An MAH employee is viewing Instagram outside the context of an ODCS activity and sees an AE/ADR mentioned regarding one of the MAH's products.

- In this example, the MAH becomes aware of AEs/ADRs on a digital platform not under the MAH's responsibility, and the MAH received the information outside of the context of an organized data collection system (ODCS).
- Although these cases are not direct communications to the MAH, if an AE/ADR collected from a digital platform outside the context of an ODCS meets reporting requirements, then it should be managed as a spontaneous report (see *ICH E2D(R1) Sections 4.3.2, Digital Platforms Not Under the Responsibility of the MAH*).
- See also *ICH E2D(R1) Section 6.1, Assessing Patient and Reporter Identifiability*, which provides guidance on the reporter and patient identifiability for cases from digital platforms.

E2B(R3) values

Type of report: *'1=Spontaneous'*
Study type: not applicable

Example 22

As part of an ODCS activity, the MAH accesses Facebook and X (not under the responsibility of the MAH) to look at abuse of their product and sees an AE/ADR mentioned.

- In this example, the MAH accesses digital platforms (Facebook and X) as a data source in the context of an organized data collection system (ODCS) activity.
- If an MAH screens or accesses data from a digital platform not under its responsibility, and the MAH's activity is conducted in a planned manner consistent with an organised data collection, the MAH should consider the activity to be an ODCS (see *ICH E2D(R1), Section 4.3.2 Digital Platforms Not Under the Responsibility of the MAH*).
- The MAH should have documentation in place as detailed in *ICH E2D(R1) Section 2.8, ODCS*.
- The MAH is not expected to search for AEs/ADRs beyond conducting its planned review of the dataset collected for the activity as detailed in its documentation.

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Example 22 (continued)

As part of an ODCS activity, the MAH accesses Facebook and X (not under the responsibility of the MAH) to look at abuse of their product and sees an AE/ADR mentioned.

- If the MAH identifies AEs/ADRs during the course of the review, the AEs/ADRs should be recorded, managed and assessed for reporting as required by regional or local requirements.
- If an AE/ADR collected from a digital platform in the context of an ODCS meets reporting requirements, it should be managed as a solicited report, and the value '6=Organised Data Collection System with source data from a digital platform' should be selected as the 'Study Type' (see *ICH E2D(R1), Section 4.3.2 Digital Platforms Not Under the Responsibility of the MAH).*
- *See also ICH E2D(R1) Section* 6.1, Assessing Patient and Reporter Identifiability, which provides guidance on the reporter and patient identifiability for cases from digital platforms).

E2B(R3) values

Type of report: *'2=Report from study'*
Study type: '6=*Organised Data Collection System with source data from a digital platform'*

Example 23

An MAH pays a lifestyle influencer to discuss a medical disease area in compliance with applicable regional and local requirements (e.g., regarding disclosure of their financial relationships to the MAH). On their YouTube and TikTok accounts, the influencer posts videos and other content about the disease area and suggests that patients talk to their healthcare provider about available treatment options.

Several of the influencer's subscribers describe AEs/ADRs for one of the MAHs products in the comments section of the influencer's posts.

- See *ICH E2D(R1) Section 6.5, Contractual Agreements*:

"Contractual agreements may take place between MAHs and third parties (e.g., service providers) who perform activities for the MAH in which they would foreseeably receive or otherwise obtain safety information associated with the MAH's medicinal product.[…]

It is important that these agreements specify the management and reporting of ICSRs (i.e., processes for exchange of safety information, including timelines and regulatory reporting responsibilities) in accordance with regional and local requirements.

Whatever the nature of the agreements, the MAH is ultimately responsible for reporting within the required timelines; therefore, the contractual partners should minimise the data exchange period to enable compliance with MAH responsibilities"

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Example 23 (continued)

An MAH pays a lifestyle influencer to discuss a medical disease area in compliance with applicable regional and local requirements (e.g., regarding disclosure of their financial relationships to the MAH). On their YouTube and TikTok accounts, the influencer posts videos and other content about the disease area and suggests that patients talk to their healthcare provider about available treatment options.

Several of the influencer's subscribers describe AEs/ADRs for one of the MAHs products in the comments section of the influencer's posts.

- In this example, the MAH's agreements should specify the exchange of AEs/ADRs reported on the influencer's platforms and ensure that processes are in place for the MAH to be able to fulfil its regulatory reporting responsibilities within the required timelines.
- The AEs/ADRs reported by subscribers are not gathered as part of an organized data collection system (ODCS), so they should be managed as spontaneous reports.

E2B(R3) values

Type of report: *'1=Spontaneous'*
Study type: not applicable

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Example 3	Patient comments about an AE/ADR on MAH's Facebook page
Example 4	AE/ADR reported on MAH corporate website (non-product related)
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Contact

- **For any questions please contact the ICH Secretariat:**

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