VigiMed: Adverse event reporting system in the use of medicines in the use of medicines

Questions and Answers Questions and Answers

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Pharmacovigilance Management - GFARM

General Management for Monitoring Products Subject to Health Surveillance - GGMON

Health Control and Monitoring Board - DIMON

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1. Generalities

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1.1	What is VigiMed?	VigiMed is the system provided by Anvisa for monitoring adverse events related to drugs and vaccines. VigiMed is the name given in Brazil to the VigiFlow system, which is provided to national pharmacovigilance centers in the member countries of the International Drug Monitoring Program by the Uppsala Monitoring Center (UMC), a WHO collaborating center that operates the Program. The adopted version of the system was released in January 2019 and some of the features are still under development, so new versions will still be released, with increments and improvements.
1.2	Who has access to VigiMed?	VigiMed must be used by State Health Surveillance and Health Services, including hospitals. Notivisa users who have not yet registered on VigiMed must continue to use Notivisa while they do not have access to the system. Citizens and health professionals with no ties to institutions can notify their cases through VigiMed's open electronic form, which does not require registration. Drug Registration Holders must continue to make their notifications on Notivisa until the specific profile for companies, still under development, is made available.
1.3	How to request access to VigiMed?	Risk managers or equivalent managers of state health surveillance and health services must send an email to vigimed@anvisa.gov.br requesting the institution's registration, informing the name, position and email of the employees who will be in charge to use the system. For new additions, the same procedure must be followed. If any employee ceases to perform such function, the exclusion of their access must also be informed by e-mail.

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1.4	How to access VigiMed?	Access to VigiMed must be done through the link sent in the email of response to registration request: vigiflow.who-umc.org
1.5	What should be reported on VigiMed?	Adverse events related to drugs and vaccines must be reported, that is, any undesirable medical occurrence in which a drug or vaccine has been administered, even if it is not certain that the intercurrence is caused by the treatment. Examples of adverse events include suspected adverse reactions, absence or reduction of effect, medication errors, interactions between different drugs and use for a purpose other than that indicated in the bubbles (off label). Technical complaints continue to be notified on Notivisa, that is, suspicions of changes in products or irregularities by companies, such as changes in the consistency of the product, label peeling off, presence of a foreign body, defect in the lid, complaints of unregistered products and counterfeit. However, technical complaints, when associated with an adverse event, must be reported on VigiMed.
1.6	What are the mandatory fields in VigiMed? on VigiMed?	It is not necessary to fill in all system fields to complete data entry. There is a minimum amount of information that the notification must contain to be valid. Mandatory fields are: • Notification information o Initial date of receipt o Type of notification o Last date of receipt (if you enter the last date of receipt, the date must be complete) o Qualification of the notifier • Patient o Patient initials or

Question #	Question	Response
		the **sex or** o **Date of birth or** o **Age at** **onset of reaction or** o **Age group** **or** o **If report is Parent Child** ÿ **Gestational age at onset of reaction** **(if fetus) or** ÿ **Gestational age at exposure (if fetus) (in** **Medicine)** • **Medication** o **Indicate at least one suspected drug or two** **interacting drugs** o **Name of** **drug (WHODrug) or** Name of drug **reported by** **the initial notifier • Reaction** o **Reaction/event as reported by the** **initial notifier** Where o **Reaction/event (MedDRA)** **However, a more complete notification will lead to a better analysis of the Report** **possible fields possible Enter as many fields as**
1.7	**What does MedDRA mean?**	**MedDRA is standardized medical terminology with the aim of facilitating the international sharing of information, it is the terminology adopted in the VigiMed system.** **In the late 1990s, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) developed the Medical Di Medical Dictionary for ctionary for Regulatory Activities (MedDRA))** **Regulatory Activities (MedDRA) - Medical Dictionary for RegulatoryActivities.**

Question #	Question	Response
1.8	How can I get help filling in the fields? fields?	Help texts are available in the icons and provide information to support data entry, such as explanations on how to fill in a particular field and information about sensitive data that will not be shared with the WHO global database. It is necessary to save the notification at the beginning of the filling in order to create the
1.9	Should the notification be saved while filling? fill?	Notification ID. If your internet connection is unstable, it is recommended to save the notification frequently to avoid losing information. By clicking on the “Save” button the last edits made to the notification are saved.
1.10	What does the red exclamation sign mean?	The exclamation point indicates that the notification may be incomplete or some data was entered incorrectly. By clicking on the icon in each section of the notification or on the “Summary” tab, it is possible to see what information is missing.
1.11	What does the vertical red bar mean?	The vertical red bar indicates that some data was entered incorrectly and the red message provides details about the error. Such flags disappear when the information is properly provided.
1.12	How to search for notifications made by my institution? institution?	After logging in, click on “Filter” in the upper right corner, establish the criteria of interest for the search (for example: notification period (start and end date), name of the drug, severity of the event, among others) and click under “Search”. If you want to search for all notifications already made by the institution, leave all search fields blank – in this case, select the blank option in the “Notification Status” field and click on “Search” or use the “Clear” button to remove the applied filters and click on “Search”.
1.13	How to export VigiMed notifications?	By clicking on the “Export” button, a PDF file is generated containing one or more selected notifications. In this same button, the “Excel” option is available, which generates a spreadsheet with the data of the

Question #	Question	Response
		notifications arranged in the “Notification List”. You can apply specific filters or select certain notifications for export.

2. Notification Information

Question #	Question	Response
2.1	What should be filled in the “Notification title” field? notification"?	The “Notification Title” is not mandatory and may follow an internal filling pattern, according to the institution's interest for better internal management of registered notifications. For example, it can be standardized internally in the institution that the title contains the hospital unit of origin of the notification or the “name of the drug + adverse event”. Example: Infirmary-1st floor; Oncology.
2.2	What is the “Type of notification” to be informed?	Most notifications are spontaneous. A “Spontaneous Notification” is an unsolicited communication provided by a healthcare professional or consumer to a company, ANVISA or other organization that describes one or more adverse reactions from a patient who has received one or more drugs and that is not derived from a study or of any organized data collection system. The other options for “Notification type” are: • “Study report” refers to reporting of reactions found in studies. By selecting this option, specific fields appear to enter study-related information and categorize it as: “Clinical studies”, “Individual patient use” (compassionate use; subject of post-study drug delivery program) or “Other studies (intensive monitoring, cohort monitoring, pharmacoepidemiology or pharmacoeconomics); • “Other” referring to those notifications that do not come from a spontaneous report or from a study or literature; • “Not available by the notifier” that allows the transmission of information by a secondary sender (e.g.,

Question #	Question	Response
		regulatory authority) where the original sender did not specify the type of notification; therefore, it differs from “Other”, which indicates that the sender knows the notification type but cannot fit it into the given categories.
2.3	What must be filled in the “Notification Status” field? notification"?	The “Notification Status” allows you to differentiate the steps in the workflow. There are three statuses for a notification: “Open”, “Under Evaluation”, and “Closed”. The notification status is also indicated in the Notification List. Every new notification is automatically set to “Open” status. After finishing editing and, if applicable, evaluating the notification, the user must change its status to “Closed” so that Anvisa can start the process of evaluating and sending notifications to the WHO database. The status “Closed” indicates that the notification is ready for Anvisa to evaluate the case.
2.4	Is it possible to include information in a notification that is in “Status Closed” that is in “Status Closed”?	Yes, it is possible to edit the notification at any time, just enter the desired notification and make the necessary changes. After completion, you must keep your status as “Closed”.
2.5	What must be filled in the “Other notification identification” field? notification identification”?	This field can be used to inform the identification of the notification adopted internally by the notifying institution, if deemed necessary for the purpose of tracking cases.
2.6	When should you check the “Parent-Child Report” option? Report”?	This option should be used in cases of notifications related to the use of medication by the father/mother, which resulted in the occurrence of an adverse event only in the child/fetus (infants, for example). The notification in such cases is referred to as the “Parent-Child Report”. If there was no reaction/event affecting the child/fetus, this type of report does not apply. For cases that describe fetal death or early miscarriage, only parental notification is applicable. If both the parent and child/fetus experience adverse events, two reports must be provided, but both must be related.

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		When selecting the “Parent-Child Report” option, it is possible to insert information related to the parent who uses the drug in the patient tab, in which the data of the child/fetus subject to the adverse event will also be described. In the “Medication” section, it will be possible to inform the “Route of administration in the father / mother”. In any case other than the clarified, this section should not be used.
2.7	How to relate two or more notifications?	Two or more notifications can be listed in the “Notification Information” section on the “Notification Identification” tab. In the “Relate notification” field, the identification of the notification with which you want to relate the case being inserted must be informed. To relate more than one notification to the case, simply click on the “Add” button.
2.8	What does the “Form of treatment” field mean?	In this field it is possible to enter the treatment pronoun by which the notifier wants to be called. For example: Sir, Madam, Miss, Doctor, Doctor.
2.9	When should the “Primary” option be checked in the “Initial notifier information” section? concerning the	The primary source of the notification is the person who first reported the facts to the sender, be it a professional, hospital, industry or Anvisa. In this case, the “Primary” option must be checked in the “Initial notifier information” block. The notification may contain more than one initial notifier depending on the intermediary mechanisms for data collection, and the primary notifier must be distinguished as such. Ex. A particular hospital uses standardized forms to notify its employees and the risk management or pharmacovigilance receives these forms and inserts them into the system. Both are from the same institution, however, the primary source would be the professional who initially provided the information through this form, for which the “Primary” option is marked. The other notifier, responsible for entering the information in the system, would be risk management or pharmacovigilance.

Question #	Question	Response
2.10	The fields “Department”, “Organization”, “Address”, “City”, “State”, “Postal code”, “Phone” and “E-mail” in the “Initial notifier information” tab refer to the patient or the notifier?	These data are related to the notifier. The fields relating to the initial notifier are optional, with the exception of the notifier's qualification. Thus, it is at the discretion of each institution to fill in (Department/organization/address/city/state/code/portal/phone of those data in all you cases one/e-mail).
2.11	When filling in the “Sender information” tab (Sender information)? (Sender information)? sender)?	The primary source of the notification is a person reporting the facts and must be distinguished from the senders (or secondary sources) who are transmitting the information (eg industry to regulatory authority). Therefore, the “Sender information” tab must be filled in when there is an intermediary in the notification process. For example: in the case of sending an xml file, the sender will be the institution or company responsible for the electronic transmission to Anvisa. It is important to note that the field “Received from” refers to the type of sender, for example if it was a health professional, patient/consumer, pharmaceutical company, etc.
2.12	When to fill in the “Literature Notification” tab? This option must be completed for cases in which the notification is based on individual cases described in the literature. In this case, literature references must be reported in "Vancouver style". This field should not be marked to cite sources of consultations (bibliographic reference) such as Bulários, PCDT, Medsafe, etc.	
2.13	What is the purpose of the “Notes” field?	This is a free text field to include internal comments about the notification that will not be exported to Excel or PDF and also will not be shared with the WHO Program.

3. Patient

Question	Question	Response
# 3.1	What should be informed about the patient?	At least one of the following data must be provided: o Patient initials or the sex or o Date of birth or o Age at onset of reaction or o Age group or Patient record or medical record number and cause of death information, because they are reported less frequently, become visible when clicking on "Additional Information." It is not necessary to fill in all patient identification fields.
3.2	When to fill in the "Date of last period" period"?	The "Date of last menstrual period" should be provided when relevant to the case assessment. You can include an incomplete date, however you must include at least the year.
3.3	Which age field must be filled in?	Patient age can be recorded in three different ways: • "Date of birth" or • "Age at time of reaction" or • "Age Group". It is recommended to record the most specific information available in the original notification.
3.4	What criteria should be adopted to select the patient's "Age group "Age group"? of the patient? of the patient?	The "Age group" field can be used in cases where it is not possible to obtain the exact age of the patient and provides an indication of this information based on an age group. • Neonate (up to 30 days) • Children (from 31 days to 05 years) • Child (from 6 to 12 years old)

Question #	Question	Response
		• Adolescent (from 13 to 18 years old) • Adult (from 19 to 64 years old) • Elderly (over 65 years old)
3.5	What does “Study Patient Identification Number” mean in patient information under “Additional information”?	The “Study Patient Identification Number” must be filled in when the notification type is “Study Notification”, that is, reports arising from adverse reactions related to drugs used in clinical research.
3.6	Where to report the “Cause of death”?	The cause of death must be recorded in the “Patient” section. When clicking on “Additional Information” the “Cause of death” field will appear, which can be informed by selecting the corresponding MedDRA term (recommended) and/or including the exact words of the notifier in free text. If an autopsy was performed, it is possible to specify the cause of death according to the autopsy in these two ways as well.

4. Case narrative and other information

Question #	Question	Response
4.1	What should be informed in the “Case narrative” field?	The purpose of the narrative is to summarize all clinical and related information relevant to the case, including patient characteristics, details of therapy, medical history, clinical course of the event(s), diagnosis(s) and ADR(s) including the outcome, laboratory evidence, and any other information that supports or refutes an adverse event. The narrative should serve as a "medical story." Information should be presented in a logical temporal sequence, ideally this should be presented in the chronology of the patient's experience and not in the chronology in which the information was received. In rectification and follow-up notifications, new information entered must be clearly identified. Abbreviations and acronyms should be avoided, with the possible exception of laboratory parameters and units. Any relevant autopsy or postmortem findings should also be summarized in the narrative. Avoid filling in data Avoid filling in data that allow the identification of the patient in this field that allow the identification of the patient in this field.

5. Medical and drug history

Question #	Question	Response
5.1	What information should be entered in the “Medical history”?	In the "Medical History" only relevant medical information prior to understanding the case should be entered, such as existing diseases (for example: diabetes, hypertension, HIV, persistent infection, etc.), surgical procedures, risk factors or conditions (such as pregnancy,). There are two options for recording medical history information: in a structured way using the fields “Relevant Medical History (MedDRA)”, Start Date”, “End Date” and “Continue” or in free text in the “Relevant Medical History” field. Relevant Medical History”. Just click the “+” icon to include new information about the medical history, that is, in case you need to inform more than one disease or condition (eg patient with a history of diabetes and hypertension).
5.2	What information should be entered in the “Medication history” section? “Drug history”? “Drug history”?	The “Drug history” must inform the relevant drugs previously used by the patient, but which were discontinued before the onset of the adverse event, including previous experiences with similar drugs, such as previous knowledge of allergic reactions to the treatment. Just click on the “+” icon to enter more than one drug.

6. reaction

Question #	Question	Response
6.1	How to describe the adverse event in the tab "Reaction"? "Reaction"?	The adverse reaction can be recorded in two ways: by including the MedDRA term (recommended) or by reporting the reaction in free text in the “Reaction/event reported by the initial reporter” field (when a MedDRA term that accurately describes the adverse reaction is not found) . The two fields can also be used in combination to reflect both the originally reported information and the ADR described in MedDRA. It should be noted that the information recorded in free text is not searchable later. It should be noted that these fields serve for the punctual description of the adverse event. Other more detailed information about the occurrence should be described in the “Case narrative and other information” tab.
6.2	How to include more than one reaction?	To register more than one reaction, just click on the “+” icon. A new section will be generated for each adverse reaction added and each of them will be listed in the side menu. Additional sections or fields can be removed by clicking on the trash can icon 
6.3	How do I search for the term MedDra?	By typing parts of words it is possible to search for MedDRA terms. The term suggestions (Lowest Level Terms (LLT)) will appear automatically. Select the term that best represents the originally reported reaction. Another option for choosing the MedDRA term is to consult the complete terminology by clicking on the icon. When selecting a term, the “Adverse reaction/event (MedDRA)” field is automatically filled in. After selecting an LLT term, by clicking on the icon it is possible to see the other LLT terms that are related to the same Preferred Term (PT). In this way, one can  easily verify if there is another more appropriate term for the reported reaction that is related to the same clinical concept of PT.

Question #	Question	Response
6.4	I did not find the MedDRA term referring to the reported adverse reaction, how do I do it?	At this time, MedDRA terms are presented in Portuguese from Portugal. This means that there may be some discrepancies in accentuation or spelling (example: vomit, fracture, cancer-meaning cancer, etc.) making it difficult to select the correct term. In cases where it is difficult to find the appropriate MedDRA term, we request that the reactions be cited in the free field "Reaction / event reported by the notifier in Medication error, with harm or without harm, event reported by the initial notifier" reported in the "Reaction" tab ". Choose the
6.5	How should I go about reporting a medication error? medication?	appropriate MedDRA term or search directly from the list of terms by clicking . The terms available for medication errors are listed in the SOC "Complications of Interventions Related to Injury and Poisoning". This SOC has terms that describe near-failure situations at different stages of the drug use process.
6.6	Gravity filling is important of the adverse event?	Filling in the severity (yes/no) is not mandatory, but it is highly recommended that it be performed by the primary notifier, as he/she was the one who had contact with the patient's clinical information. When a reaction is classified as "Severe", it is mandatory to select at least one severity criterion. Severity and severity criteria are associated with a specific reaction, that is, they must be reported for each of the reported reactions. This information is very important as it serves as a criterion for defining regulatory reporting obligations.
6.7	What does the "Recovered/ Resolved" option in the "Outcome" field mean? "Outcome"?	The option "Recovered/Resolved" means that the outcome of the reported reactions was resolved without sequelae. It is also possible to inform as an outcome "Recovered/Resolved with sequelae".
6.8	How to report that the patient died as a result of an adverse event? as a result of an adverse event?	To describe the death, it is necessary to select the "Fatal/Death" option in the "Outcome" field. The severity of the reaction must also be informed by checking the option "Resulted in death". In general, death should not be

Question #	Question	Response
		registered as “Adverse reaction/event”. The one filled “Cause of Death” must be in “Additional Information” in the “Patient” section and also reported in the “Narrative”.
6.9	Is there no field to record the intensity of adverse reactions (mild, moderate, severe)?	There are no fields for recording the intensity of the reactions, only for the severity, in the case of severe reactions. According to the need, the description of intensity can be inserted in the narrative in order to better characterize the event. Another option is to use the “Reaction/event reported by the initial notifier” field to be more specific. Example: if the reported reaction was “severe headache”, MedDRA LLT could be selected “Headache” and under “Reaction/event reported by the initial notifier” write “severe headache”.

7. Medication

Question	Question	Response
# 7.1	What does the field “Relationship between medication and the event”?	It is a mandatory field that must be used to indicate the role of the drug in the event, that is, if it is “Suspect”, “Concomitant”, involved in an “Interaction” or drug not administered”. Causality assessment is available only for drugs characterized as “Suspect” or “Interaction”.
7.2	In the field “Relationship between the drug and the event”, when the “Drug not administered” option?	“Medication not administered” can be used in two circumstances: • in the clinical trial: if the adverse event occurred after the informed consent was signed, but before the administration of study drug (eg, during the screening or washout procedure), the adverse event should be reported generally as per the clinical trial. study procedure; in case of medication error: if the patient did not receive the prescribed drug, but another one, the “Medication” section must be filled in with the information about the prescribed drug (including the fact that it was not administered) as well as the information about the drug dispensed as "Suspect". Medication error should be captured with the appropriate MedDRA term in the “Reaction” section.
7.3	How to notify a suspected interaction?	If the notifier indicates a suspected interaction with other drug(s), 'Interaction' must be selected for all drugs suspected of interaction, in the “Relationship between drug and event” field. If an interaction with food or other non-drug compounds is suspected, "Interaction" must be selected for the reported drug. The type of interaction (eg drug interaction, food interaction, alcohol interaction, etc.) must be reported with the appropriate MedDRA terms in the “Reaction” section, along with any event resulting from the suspected interaction.

Question #	Question	Response
7.4	How to enter cases of ineffectiveness?	In the “Reaction” section, the MedDRA term “Ineffective drug” should be selected. In cases of suspected drug ineffectiveness, it is important to identify the “Batch number, in the “Drug” section.
7.5	How to inform the name of the drug?	The drug name can be registered in two ways: including the term WHODrug (recommended) or in free text stating the drug name as reported by the initial notifier. The insertion of the drug name in free text must be done when the drug reported by the notifier is different from the name found in the WHODrug or when it is not possible to find the right drug in the WHODrug. The two fields can also be used in combination to reflect the information originally reported. It should be noted that the information recorded in free text is not searchable later. You can search by trade names or active ingredients. For this, it is necessary to enter the full name or parts of the drug name in the respective field. A list of matching results will automatically appear. To ensure that the best result is chosen, you can click on the icon to check active ingredients and ATC codes. To search
7.6	How to look up the drug name in WHODrug? WHODrug?	for drug associations, leave a space or use a comma “,” between words. For example, the association valsartan + hydrochlorothiazide can be found by typing: “hydrochlorothiazide, vals”. If no suitable option is found, you can write “valsartan + hydrochlorothiazide” in the free text field “Drug name as reported by initial notifier”.
7.7	How to include more than one drug?	To register more than one drug, click on the “+” icon at the beginning of the section. The sections will be repeated as a whole. For each repeated section, a specific item will appear in the section menu of the notification. Additional sections or fields can be removed by clicking the trash can icon This field indicates whether the notification is also related to any of the
7.8	What does “Additional drug-related problems” mean? drug related”?	scenarios listed below:

Question #	Question	Response
		•Falsificação •Overdose •Medication taken by the father •Medication taken beyond the expiration date • Batches tested and within specifications • Batches tested and out of specifications • Medication Error • Incorrect use •Abuso • Occupational exposure • Off-label use This can make it easier to search for similar reports. The drug-related problem should also be included as a reaction with the corresponding MedDRA term.
7.9	In the “Additional drug-related problems” field, are the options “Medication error” and “Incorrect use” equivalent?	The two terms are not equivalent. The “Medication Error” is related to an accidental, unintentional situation. In the case of “Incorrect use”, the medication is used incorrectly in an improper and intentional way. We adopt the following settings in this case: • *Medication Error: An unintentional failure in the treatment process with a medication that causes or has the potential to cause harm to the patient. • *Incorrect use of a drug: situations where a drug is intentionally misused, not in accordance with the terms defined by the registration holder. *EMA-PRAC Good Practice Guide on Recording, Coding, Reporting and Assessment of Medication Errors, 23 October 2015.

Question #	Question	Response
7.10	In the field “Additional drug-related problems”, what does the option “Off label use” mean? off-label”?	“Off-label use” is the intentional use of a drug, indicated by a health professional, for therapeutic purposes in a different way from what is registered in the package insert.
7.11	In the field “Additional drug-related problems”, when should the drug option “Father” selecting the option "Medication taken by father"?	This field refers to parenteral exposure, for example, when the drug was used by the father or mother, but the reaction was observed in the child, fetus or newborn. This option must be used in the case of notifications related to parental exposure, to insert information related to the father or mother, that is, the one who used the drug. Information about the father or mother should only be filled in when the reaction is observed in the child/ fetus in which the father/mother had no reaction. In this case, the “Parent-Child Report” option must be checked in the first notification session: “Notification Information”.
7.12	When to inform the “Interval between the administration of the drug and the beginning of the reaction”? reaction"?	Even when other dates are provided when completing the notification, this information is also useful in situations where the interval to the onset of the reaction is very short, such as in cases of anaphylaxis or arrhythmia, or when the known dates are inaccurate, but there is information about the range.

8. Tests and procedures

Question #	Question	Response
8.1	How do I find the proper MedDRA term to enter the “Test Name”? to enter the “Test Name”?	When it is difficult to identify the MedDRA term of procedures and exams, search for the alternatives available in the SOC “Complementary diagnostic exams”, by clicking on the icon. 
8.2	How to proceed if the unit of measurement to record the test is not found” or “Result of “Result of test result” or the test “or is expressed is expressed is expressed unit unit unit measure? measure?	In these cases, you must inform the results in the free text field.

9. Evaluation

Question #	Question	Response
9.1	Can I carry out a causality assessment of my own notification? my own notification?	Both the primary notifier and the other entities of the National Health Surveillance System will be able to carry out causality assessments without the others being invalidated in the fields intended for each institution. If there is already a causality assessment present in the notification, simply click on the “+” sign next to the “Causality assessment” heading and enter the new causality assessment.
9.2	What should be filled in the “Comments” field? "Comments"?	This field is intended for the evaluator's comments and can be described in it observations about the evaluation, such as whether the reaction is expected, described in the leaflet, etc. In cases where there is no agreement with the initial notifier's diagnosis or if there are alternative diagnoses or additional comments, you can enter them in these two fields (diagnosis and comments).
9.3	Where should the sources consulted to carry consulted to carry out the bibliographic references notification be recorded? notification evaluation?	There is no specific field to record this information. You can use the “Comments” field.

10. Historical

Data	Version	Changes	Comments
18/07/2019	1.0	First version	Initial document version

11. References

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