

115632 – WEB-RADR

**WEB- Recognising Adverse
Drug Reactions**

**Pilot project patient-
friendly terms**

Report results pilot project

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2 Background

Previously, a mobile app for patients and healthcare professionals (HCPs) to report adverse drug reactions (ADRs) and to receive medicinal product information – i.e. two-way risk communication – has been developed. Currently, four versions of the app are available, one for the UK, one for the Netherlands, one for Croatia, and one generic version (country-independent). Several studies have been conducted to evaluate the app. An example is a qualitative study in which factors influencing use of the app were assessed during focus group discussions and face-to-face interviews with patients and HCPs (1). One of the identified influencing factors was the used language in the app. It was mentioned that the terminology in the app should be appropriate for app users, implying that lay-terms should be used in the app for patients whereas medical terms should be used in the app for HCPs.

The app contains an overview of previously reported ADRs per drug. Also, people can select an ADR from a list when they report an ADR. Currently, the terminology in this overview and list is based on the Medical Dictionary for Regulatory Activities (MedDRA®). The MedDRA® is developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and is a medical dictionary containing standardized medical terminology (<https://www.meddra.org/>). The MedDRA consists five levels ranging from very general to very specific terms. The five levels are System Organ Class, High Level Group Term, High level Term, Preferred Term and Lowest Level Term (LLT). The terminology used in the MedDRA fits HCPs' language but is generally less suitable for patients. Patient-friendly terms are important in tools that are used by patients (2). Some work has been conducted to develop patient-friendly terms, for instance about health/medical concepts (3-5) and to link a list with 252 ADRs in lay-terms in a questionnaire for patients to the MedDRA® (6). Also, there are some online symptom checkers for patients that contain lay-term symptoms. An example is the WebMD symptom checker (<http://symptoms.webmd.com/#introView>) in which patients can select symptoms via a search function or via a body map.

Recently, a patient-friendly terms list of the MedDRA® has been developed by MedDRA Maintenance and Support Services Organization (MSSO) in which verbatim text from patient-reported ADRs and associated MedDRA terms at LLT level (linked to the texts by authorities) was used. The list reflects the language that has been used by patients submitting ADR reports using online forms in recent years but is not (yet) comprehensive.

The goal of this pilot project was to evaluate patient-friendly terms in the reporting of ADRs to the national pharmacovigilance center. The patient-friendly terms list was available in the English language only at the time of this study. Therefore, the pilot project focused on the ADR report form of the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK, the YellowCard form.

2.1 Objectives

This pilot project consists of three parts with the following aims:

1. to assess patients' perspectives on patient-friendly terms in the report form: preferences for the presentation of the terms and evaluation of the terminology developed by MSSO;
2. to evaluate the usefulness of patient-friendly terms in the report form;
3. to evaluate actual use of patient-friendly terms in the report form.

3 Methods

This study was part of the work conducted by members of the Web-Recognizing Adverse Drug Reactions (Web-RADR) project (<https://web-radr.eu/>). The methods used in this study are described below per study part.

3.1 Part 1. Patients' perspectives on patient-friendly terms in the report form

For this part, a qualitative study design was used in which patients were asked to report their views on patient-friendly terms in the report form.

An information letter about the study was sent to patients in the EURORDIS UK network and the Patient Group Consultative Forum (PGCF). This information letter contained information about the study using focus groups. Patients interested in participation could respond by email and indicate their availability in an online dateplanner. Since only a few patients could attend a specific focus group session, the study method was adapted to a survey study containing particularly open-ended questions. This increased the feasibility for patients to participate. Patients interested (N=10) in the study were asked to complete the survey and return it by email. Participants did not receive any (financial) compensation for participation. Completing the survey was considered as providing consent to participate in the study.

The survey contained questions about characteristics of the responder (i.e. age, gender, patient's experiences with side-effects, and patient's experiences with searching for information about side-effects for instance on the internet), questions about reporting side-effects (i.e. experiences with reporting side-effects to the MHRA, and preferences on how to describe the side-effect in the report form), and questions on the use of standard terms for side-effects in the report form (i.e. usefulness, advantages/disadvantages, presentation). Finally, patients were asked in the survey to evaluate 40 randomly selected terms from the patient-friendly terms list developed by MSSO on their understandability.

MSSO identified 278 terms at LLT level from the patient-friendly list as *potentially difficult* terms for patients. These terms were evaluated in the survey. Eight versions of the survey were used, each containing a subset of the terms from this list. In addition, a randomly selected sample of 23 terms that were considered *probably understandable* were divided over the eight versions of the survey and were also evaluated by the patients. Patients were asked to indicate for each term whether the term was in their opinion unclear/difficult or clear/easy and whether the term would be (un)clear for other people they know. In addition, they could indicate any suggestions for improving each term or they could add any comments.

The surveys returned by the patients were collected by MHRA project members who forwarded them to the UMCG project members. The project members from the UMCG stored the surveys.

Thematic analysis was used to identify themes or patterns in the responses of the patients to the open-ended questions. Results of the evaluation of the specific terms are presented descriptively.

3.2 Part 2. Evaluation of the usefulness of patient terms in the report form

For the second part, a short, online survey was used. Patients who reported an ADR through the YellowCard online form were asked to complete this survey about their experiences with describing the side-effect in the form. The patient-friendly terms developed by MSSO were integrated in the online form before this survey study started. Patients completed the survey between August 2, 2017 and September 22, 2017. Completing the survey was considered as providing consent to participate in this study. Participants did not receive any (financial) compensation for participation in the study.

The online survey was developed using Qualtrics software (www.qualtrics.com) and contained open- and closed-ended questions. Questions were about demographics, how the patient entered the side-effect in the report form (i.e. using free-texts or selecting a symptom from a list that appeared), and reasons for and experiences with the used method.

Due to the use of an online survey, the data were directly entered in a database which eradicates potential data-entering errors. The project members from the UMCG stored the raw data on a local, secured disk. A copy of the raw data was used for the data cleaning and data analyses.

Cleaning of the data included deletion of responders who did not complete the survey and where necessary/desirable (re)naming of variables, labelling of variables, labelling of values, etc.

The data were analysed descriptively and summaries are given of responses to the open-ended questions.

3.3 Part 3. Evaluation of actual use of the patient terms in the report form

For this part, actual reports sent by patients after the patient-friendly terms had been incorporated in the YellowCard online form were used.

The following questions were assessed in this part:

- How many of the patients who reported an ADR through the online report form selected an ADR from the list versus how many entered the ADR themselves?
- Which terms were selected from the list?
- Which terms were entered by the patients themselves?
- Are patient characteristics (i.e. sex, age) associated with using the patient-friendly terms?

Also, it was assessed how many of the reported ADRs were classified on MSSO's list of *potentially difficult* terms and *probably understandable* terms.

The data were extracted by MHRA project members and analysed by UMCG project members. The UMCG project members stored the data and the script that was used for the analyses. Descriptive statistics were used for a description of the included population and answering the research questions. For the last research question, a chi-square test and t-test were used to test the association between the use of the patient-friendly terms and respectively sex and age of the person for which the ADR was reported.

3.4 Ethical considerations - Regulatory and Ethical compliance

Formal ethical evaluation was not considered necessary very the studies described in this report since the methods used were non-invasive for patients and most of the data was collected using the results from the MHRA's structural work activities.

4 Results

4.1 Part 1. Patients' perspectives on patient-friendly terms in the report form

4.1.1 Responder characteristics

Ten patients were sent the open-ended survey about their perspectives on the patient-friendly terms in the report form. Four of them returned the survey. The age of these patients ranged from 27 to 72 and three patients were male. All patients had ever experienced a side-effect in their life.

One patient had never searched for information about side-effects whereas the other three patients did search for information. All of these patients searched on the internet (e.g. Google, NHS website) for side-effects associated with specific drugs and for additional information (e.g. *"what could be done to reduce symptoms"*). One patient additionally looked in the patient information leaflet and used a patient forum for such information.

4.1.2 Reporting side-effects

None of the patients had ever reported a side-effect to the MHRA. Therefore, no experiences were shared about the way in which the side-effect have to be entered in the report form. Two patients indicated that they discussed the side-effect with a HCP but one patient was not sure whether the HCP believed that the symptoms were a side-effect of a drug.

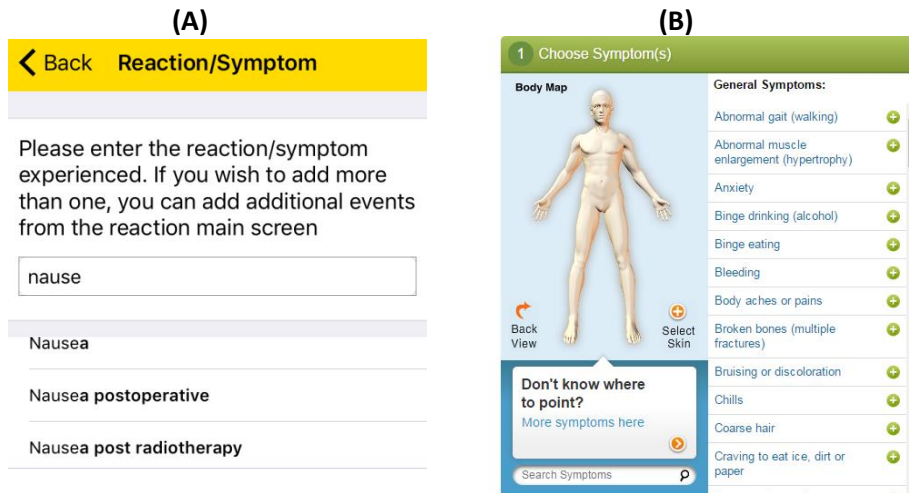
All patients indicated that they would prefer to describe the side-effect in their own words rather than selecting a term from a list. Patients indicated that they can provide more accurate information when describing the side-effect themselves and that this will not confront them with medical terms:

- *"I think by describing the side effects myself I can describe things better and more accurately"*
- *"I'd prefer to describe it in my own words as I've limited medical knowledge of terms and jargon"*
- *"Don't see that a list would be helpful to me personally because I am capable of adequately explaining symptoms and expressing how I feel..... generally I know when I am feeling terrible and can figure out what could/might be a cause. Maybe some people can't explain how they are feeling and prefer a list. This may be desirable where English isn't first language and patients don't know how to explain"*
- *"Side-effects can affect patients very differently, and there are so many variables that a tick-box multiple choice approach could be limiting at best, and inaccurate at worst"*

4.1.3 The use of standard terms for side-effects in the report form

Patients indicated that the use of standard terms in the side-effect form could be a good idea A) for people who cannot express themselves, B) as a starting point but there will be a need for an opportunity to add more details, and C) if the use is tailored to non-medical people.

In the survey, two examples of the presentation of standard terms in the side-effect reporting form were presented. In example A, terms would be suggested after someone enters a few letters of a side-effect. In example B, the person reporting the side-effect could select a body part after which he/she could select the side-effect from a list that appears for that body part:



There was discordance in patients' preferences towards these presentation forms:

- *“In A a lot of people will not understand the terms and therefore will fail to complete the form. B will allow you to consider a large number of side effects and report on them and will prompt you. Easier to understand that a lot of medical terms that most people will not understand”*
- *“prefer the layout and simplicity of B but think A involves fewer clicks and is therefore less hassle to complete.”*
- *“Advantages in first example better than in the second because there is a set condition and set side-effects. Second example more complicated as there are so many different conditions that can cause problems. Like the box don't know where to point – I can understand that one.”*
- *“Prefer drop box options, but even that has the danger of a patient selecting the wrong box and/or not understanding what the terms mean. Diagram is not helpful, as we are not doctors.”*

It was mentioned that the use of standard terms for side-effects in the reporting form should be presented in non-medical terms and there should be an option to fully describe the side-effect and report side-effects that are not in the list. Patients indicated that at least 3 letters have to be entered before a drop-down list should appear. One patient, however, indicated that it could *“give rise to ambiguity if several <side-effects> start with same 3 letters”*.

4.1.4 Evaluation of selected terms

Three patients evaluated 40 terms that were selected from the patient-friendly list. One patient started evaluating the terms but had to quit after 3 terms because of limited time. Therefore, a total of 123 patient-friendly terms (i.e. 114 potentially difficult and 9 probably understandable terms) were evaluated by one person.

Of the 114 potentially difficult terms:

- 60 terms were *unclear* for the patient and considered to be *unclear* for other people;
- 36 terms were *clear* for the patient and considered to be *clear* for other people;
- 17 terms were *clear* for the patient but considered to be *unclear* for other people;
- 1 terms was *unclear* for the patient and an evaluation for other people was lacking.

		Other people	
		Unclear	Clear
Patient him-/herself	Unclear	60	1
	Clear	17	36

Of the 9 probably understandable terms:

- 2 terms were *unclear* for the patient and considered *unclear* for other people;
- 7 terms were *clear* for the patient and considered *clear* for other people.

		Other people	
		Unclear	Clear
Patient him-/herself	Unclear	2	0
	Clear	0	7

A few suggestions for improving the terms were given. For two terms, it was indicated that the age of the patient could influence whether the person understands the term. More specifically, it was mentioned that older people or older than a specific age might be more aware of a specific symptom. The full list with evaluated terms and suggestions/remarks is presented in Appendix 1 (Chapter 8).

4.2 Part 2. Evaluation of the usefulness of patient terms in the report form

The number of patients that completed the online survey was 56. Most of these patients were female (80%). The age of the responders ranged from 20 to 78 years (average: 50, standard deviation: 15). Most patients entered the side-effect in the report form by fully typing the side-effect in the free-text field. This was the case for both, the options that were tried and the final option used (Figure 1A + Figure 1B). Most of the patients who tried only one option also used that option in the end (Figure 1C). Eleven percent of the patients tried both options (i.e. fully typing the side-effect in the free-text field and typing a few letters and select the term from a list that appears). Of these 11% of the patients, most patients in the end chose to type a few letters and select the side-effect from the list that appeared (9% versus 2% who fully typed the side-effect in the free-text field) (Figure 1C).

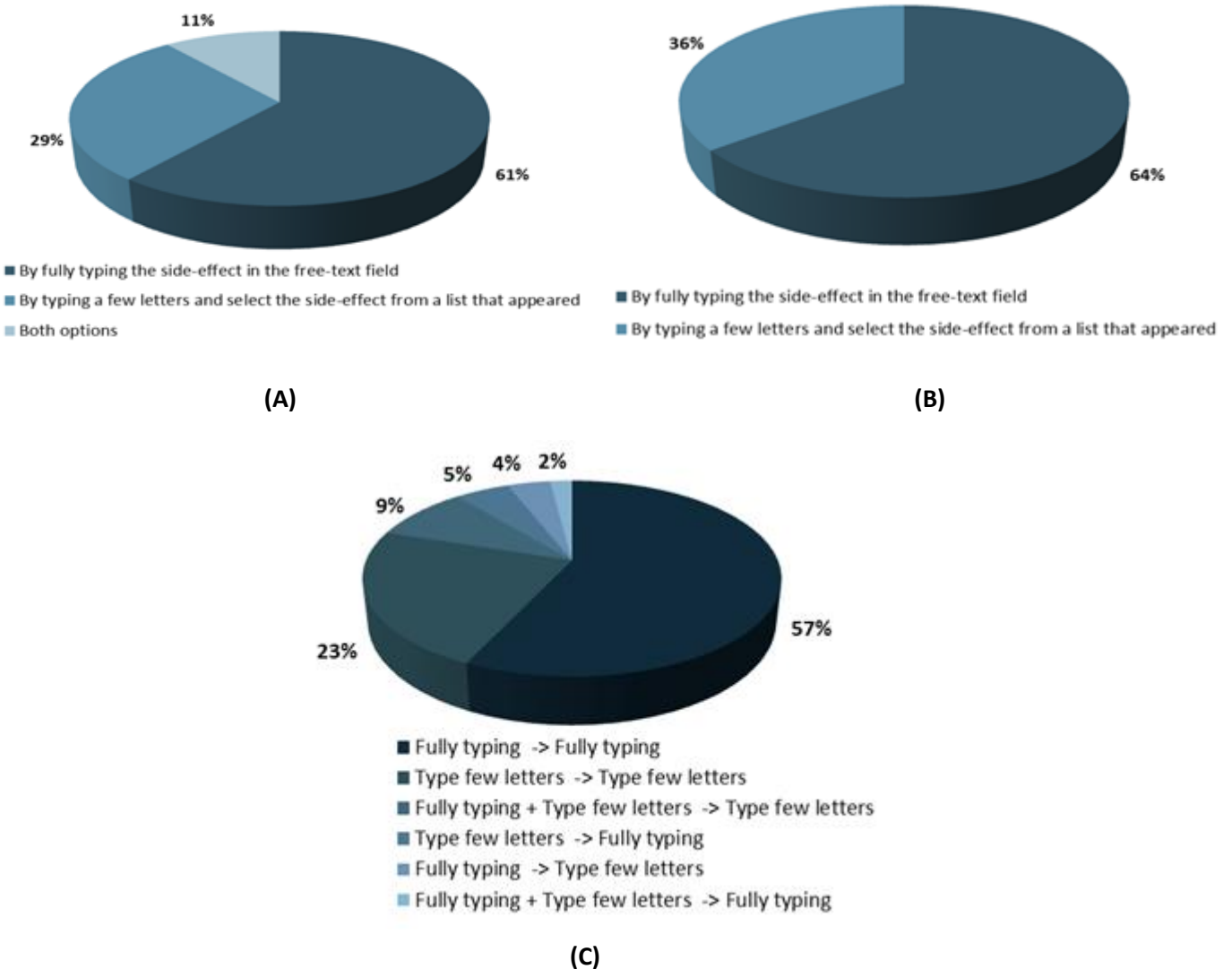


Figure 1. A. Options that patients tried when they had to enter the side-effect in the report form. **B.** Option that patients finally used to enter the side-effect in the report form. **C.** Combination of options tried and option finally used.

Patients received different follow-up questions depending on the answers given on the questions about the option(s) tried and used for the reporting of side-effects. There were three different groups for the follow-up questions:

- *Group 1*: Those who only used the option ‘By fully typing the side-effect in the free-text field’ (on both questions): N = 32 (57%)
- *Group 2*: Those who in the end used the option ‘By typing a few letters and select the side-effect from a list that appeared’: N = 20 (36%)
- *Group 3*: Those who tried the option ‘By typing a few letters and select the side-effect from a list that appeared’ but who finally used ‘By fully typing the side-effect in the free-text field’: N = 4 (7%).

4.2.1 Group 1: Patients who only fully typed the side-effect in the free-text field (N=32)

More than 80% of these patients found it (very) easy to fully enter the side-effect in the report form (Figure 2).

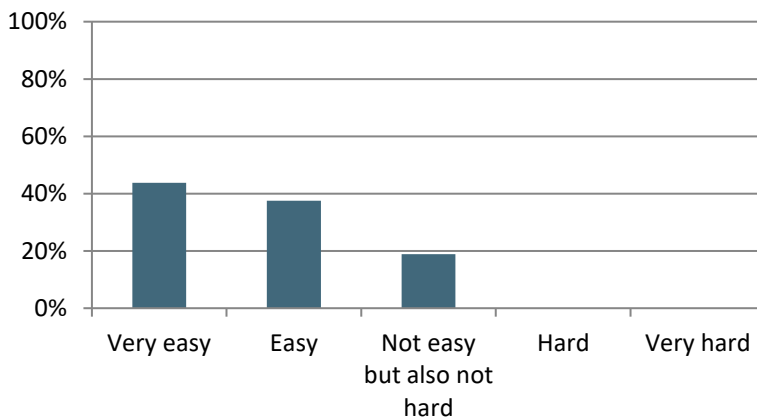


Figure 2. Results of the question ‘How easy or hard was it for you to fully enter the side-effect yourself?’ for group 1.

Most patients did not answer the question ‘What are your experiences with fully entering the side-effect yourself?’ or indicated that it is ‘simple’, ‘fine’, ‘OK’, etc. Entering the side-effect by the patient him-/herself was seen as having the option to accurately provide exact details. A disadvantage related to this process that was mentioned relates to not being sure about how much information to enter / whether all relevant details have been given. One patient indicated that the option to pick a term from a list did not appear. Two other specific issues were mentioned:

- *“What do you mean? It probably takes longer than having predictive text but at least I know what I type is recorded”*
- *“Annoyingly only the details from one of the side effects reported appear on the final report submitted. I tried editing this side effect but the field that needed editing was not included on the page, so now my report looks as if only one symptom applies to all of the side effects I reported”*

Only a few patients made some comments or suggestions to improve this step in the reporting of side-effects. The comments and suggestions are:

Report form in general:

- *“Possible difficulty for individual with dyslexia or problems with processing to communicate to written form”*
- *“There seemed to be several places where you had to type the same information more than once”*
- *“No. Except the online form(s) are confusing, duplicate questions and make a simple reporting system”*
- *“Please sort out the edit facility :)”*
- *“Yes it should be done by a mental health specialist at the time of the incident”*

Related to the text box:

- *“Perhaps to suggest entering main side effect first, then any other minor ones that you just put up with”*
- *“Well a larger text box would be beneficial”*

List with terms:

- *“List of side effects to choose from”*
- *“I didn't notice any option of a pick list”*
- *“Would have liked a prompt perhaps, or brief explanation so I know I'm using the correct terminology”*
- *“Using a drop down menu ensures correct spelling; requires use of both medical and common words. Also required a free tekst box in case the side effect is not listed”*

4.2.2 Group 2: Patients who in the end typed a few letters and selected the side-effect from a list (N=20)

Patients who in the end used the list to select their side-effect found this list generally (very) helpful. Only 15% of the patients had a neutral or negative view (Figure 3A). Moreover, 90% of the patients found it (very) easy to find their side-effect in the list (Figure 3B). All patients indicated that they had not seen any terms that were too technical, medically challenging or unclear to them.

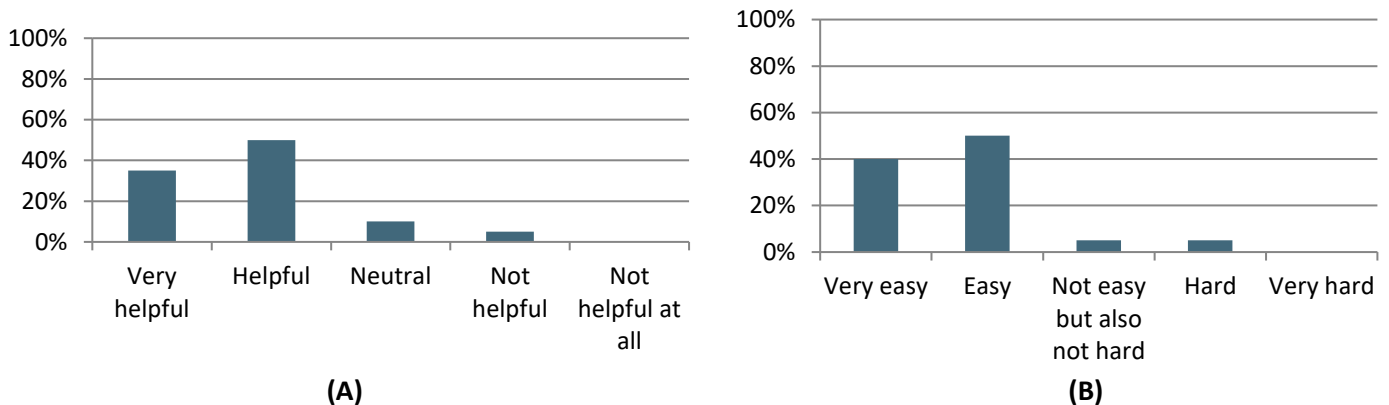


Figure 3. A. Results of the question ‘How helpful was the list with side-effects for you? **B.** Results of the question ‘How easy or hard was it for you to find the side-effect in the list?’.

On the open-ended question ‘What do you think of the way the terms are presented’ seven patients did not report anything whereas the other patients indicated it to be ‘Ok’, ‘Fine’, ‘Clear’. Two more detailed answers are:

- *“Very easy to understand. Info is on packet and in leaflet just a case of matching it up”*
- *“While I am a patient in this instance, I am a physician so medical terms as options would be good”*

Only two patients gave suggestions on the question ‘Do you have any comments or suggestions to improve this step in the reporting of side-effects?’. The suggestions given related to the reporting form in general:

- *“Less personal information might put people off filling out a yellow card”*
- *“There could be pointers on where to find the correct info on packets. Such as batch numbers etc”*

4.2.3 Group 3: Patients typing a few letters but in the end fully typed the side-effect themselves (N=4)

The answer options for the question ‘Why did you choose to type in the side-effect yourself?’ were all selected by one patient. One other patient selected two options. The answer options were:

- I prefer to type the side-effect myself (N = 2)
- The side-effects from the list were described in a too technical, medical or unclear way (N = 1)
- My side-effect was not included in the list (N = 2)

There were no patients who selected the other answer option.

Most patients (N = 3) found it easy to fully enter the side-effect themselves (Figure 4).

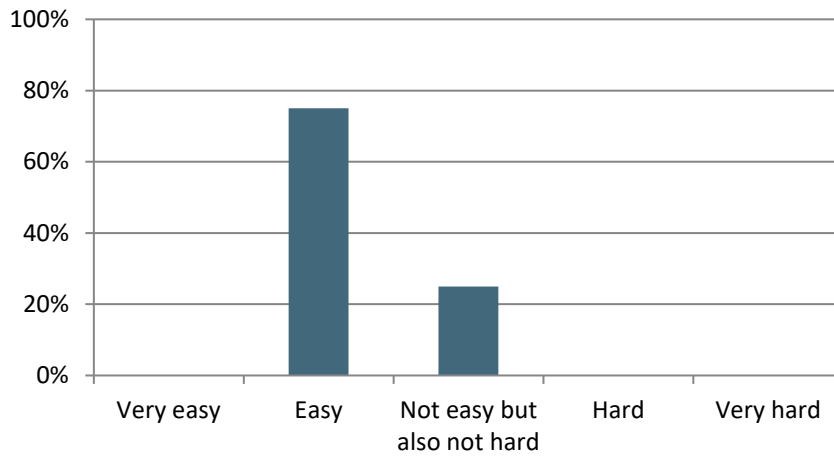


Figure 4. Results of the question 'How easy or hard was it for you to fully enter the side-effect yourself?' for group 3.

One patient answered the open-ended question 'Wat are your experiences with fully entering the side-effect yourself?':

- *"Ok, I could be more accurate"*

No further comments or suggestions were given by these patients.

4.3 Part 3. Evaluation of actual use of the patient terms in the report form

In the period August 2, 2017 to September 18, 2017, 889 ADR reports submitted by a patient, parent, or carer were received by the MHRA via the online reporting form. In 69% of the cases, the report was about a female. An age was entered in 857 reports (96%) and ranged from 0 to 94 years (mean: 43, SD: 21) (Table 2).

Table 2. Characteristics of the ADR reports

	Overall	Those not using the patient-friendly terms list	Those using the patient-friendly terms list	P-value
N reports (%)	889	670 (95)	219 (5)	
Sex				0.256
Female	614 (69)	453 (68)	161 (74)	
Male	271 (30)	214 (32)	57 (26)	
Unknown	4 (0)	3 (0)	1 (0)	
Age, mean (SD)	43 (21)	46 (21)	36 (18)	<0.001
Overall N of ADRs at LLT level	3,233	2,776	457	
Most commonly reported ADRs (N)	Nausea (79) Headache (77) Dizziness (54) Diarrhoea (54)	Headache (69) Nausea (62) Dizziness (40) Diarrhoea (39)	Nausea (17) Diarrhoea (15) Dizziness (14) Vomiting (11)	
N of different ADRs at LLT level	1,153	1,088	249	

ADR = Adverse drug reaction; SD = Standard deviation; LLT = Lowest Level Term

In 219 reports (5%), the reporter used the patient-friendly terms list to enter the ADR(s) (Table 2). The sex of the reporters who used the list did not significantly differ from the reporters who did not use the list. However, those using the list were generally younger than those not using the list (on average 36 years versus 46 years; $P < 0.001$).

In total, the reports contained 3,233 ADRs at LLT level. Of them, 457 were reported by reporters who used the patient-friendly terms list. The most common LLTs reported by those using the patient-friendly list were nausea (N=17), diarrhoea (N=15), dizziness (N=14), and vomiting (N=11). The most common ADRs of the other reporters were headache (N=69), nausea (N=62), dizziness (N=40), and diarrhoea (N=39) (Table 3).

The number of LLTs that were reported only once was 682 with 59 (9%) of them only in the reports of those using the patient-friendly terms list.

Itching was the ADR with the highest number (N=19) of reports by those not using the list and zero reports from those using the list. Restless legs was the ADR with the highest number (N=3) of reports by those using the patient-friendly terms list and zero report from those not using the list (Table 3).

In total, 1,153 different ADRs at LLT level were reported. Five percent of them (N=53) was an ADR on the *potentially difficult* terms list. Most of these (N=40) were in the reports from patients who did not use the patient-friendly terms list. Seven of the potentially difficult ADRs were mentioned only by those using the patient-friendly terms list.

5 Discussion

This report described three studies evaluating the potential value of a patient-friendly terms list. Also, the understandability and usefulness of a recently developed list with patient-friendly terms was pilot-tested. The studies show that patients generally describe symptoms in their own words in the ADR report form rather than selecting symptoms from a list. However, people who used the list were positive about its usefulness.

The use of pre-defined terms may have advantages for the handling of ADR reports, e.g. it may save time if pharmacovigilance experts do not need to reduce a description of an ADR to single terms. However, patients in our study indicated that selecting terms from a list will limit the information that they can provide about the ADR. Previously it has been shown that patients provide richer, more detailed, information about ADRs in a report than HCPs (7). Another aspect mentioned by patients was that symptoms can be classified incorrectly if terms are selected from a list. A previous study showed that the agreement between HCP-reported ADRs and the corresponding MedDRA terms was suboptimal with differences between professions. The authors suggest terminology training to improve the quality of ADR reports (8). Such a training will be unfeasible for every patient. These aspects indicate that there will be a need for patients to continue describing their ADR in their own words and in more detail than to only be able to select terms from a list.

From the patient perspective there does not seem to be a high need to change the free-text field for entering the ADR. Most patients in our study (second study in this report) found it easy to enter this information in the report form. On the other hand, most of the patients who tried both options for entering the ADR (i.e. enter the ADR in a free text field as well as select a term from a list) in the end chose to type a few letters and select the ADR from the list. This finding indicates that if patients are aware of this option, it may be preferred over entering the ADR in a free text field. However, numbers are small and this should be confirmed in future studies. Given the concerns reported in the previous paragraph, future studies should also assess whether the quality of the reports is similar between reports in which the ADR is reported in the free-text field versus those in which the ADR is selected from the list.

The understandability of a sample of terms from the patient-friendly list was evaluated in the first study. Many terms that were considered by MSSO as *potentially difficult* were indeed unclear for patients. Also, about one fifth of the evaluated *probably understandable* terms were considered to be unclear by the patients. This indicated that the patient-friendly terms list needs to be improved. Previously, it has been stated that patients should be more often involved in research studies (9). Our findings suggest that this involvement also applies to the development of a list with patient-friendly terms. Input from patients is crucial in this development.

The results of our studies suggest that the age of a patient may influence whether or not the patient-friendly terms list is used and whether or not a patient understands the presented patient-friendly terms. Previous studies have also shown an association between age and understanding medical terms. Increasing age was associated with higher scores on tests about knowledge of medical terms (10,11). This is in line with the result of our first study in which patients indicated that older people or people from a certain age may be more aware/familiar with some specific terms than younger people. Interestingly, the results from our third study showed that those using the patient-friendly terms list were generally younger than those not using the list. More research is needed to assess the association between age and the interpretation of symptoms from the patient-friendly list.

The studies described in this report gave some suggestions and ideas to consider when further developing the patient-friendly terms list in the ADR report form. For instance, a brief explanation of a term could improve understandability and when to present the patient-friendly terms instead

of terminology used for HCPs (e.g. someone completing a report form as a patient but being a HCP as well). Also, suggestions to improve the ADR report form in general were giving such as presenting a larger box for entering the ADR and to add information about where to find information that is asked for (e.g. batch numbers). These suggestions could be considered to further improve the patient-friendly terms list and the ADR report form.

5.1.1 Strengths and limitations

This was the first pilot project to evaluate the usefulness of a patient-friendly terms list. Three different studies were used to evaluate the use of such a list in general and to evaluate a specific version. Therefore, various aspects have been evaluated.

A limitation of the first study described in this report is that the included patients had never reported an ADR to the MHRA. Therefore, they didn't have any experience with entering an ADR in a report form and their perspectives may differ from patients who actually reported an ADR. Also the low number of patients included in that study should be noticed. Due to this, only a sample of the potentially difficult terms were evaluated. Moreover, the terms that were evaluated were only evaluated by one patient.

Another limitation is the uncertainty of a representative sample of responders to the surveys. Responders to the survey in the second study were more often female (80% versus 69%) and somewhat older (on average 50 years versus 43 years) than patients for which an ADR was reported in the third study. This may indicate that the included sample was not fully representative for the total population of patients reporting ADRs. However, it should be noted that the patient for which an ADR was reported is not necessarily the same person as the one sending the report. An example is a parent reporting an ADR for a child. However, the number of cases aged less than 18 years was small (N=79).

Furthermore, we assessed the understandability of terms using someone's own subjective evaluation. Future study using for instance word tests should also be used to assess whether patients have the correct meaning for the terms.

In the second study, some patients indicated that they were not aware of the list with ADRs appearing in the ADR report form. Therefore, these patients were not able to use the list. It is advised to evaluate how many letters need to be entered before the list will appear. It might be considered to shorten the number of letters.

It should also be noted that this study was conducted with the patient-friendly terms list in the online report form whereas ultimately, this list is also used in the mobile app. The use of such a list may be different in an app.

Finally, it should be noted that the studies focused on using the patient-friendly terms list in the ADR report form. For the app on two-way risk communication, this list can also be used in the communication about ADRs to patients or providing an overview of ADRs previously reported to a specific drug. The use of patient-friendly terms in such communications may be somewhat different than presenting the list in the ADR report form since additional information can be provided in the communications. Future studies should be conducted to assess the role of patient-friendly terms in such communications.

5.2 Conclusion

A patient-friendly terms list might be a useful feature in an ADR report form but should not replace the option for patients to describe the ADR in their own words. Such a list should, however, be developed in collaboration with patients and extensively tested to guarantee its understandability.

6 References

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7 Appendix 1. Evaluated patient-friendly terms – Study 1

7.1 Overview of evaluated potentially difficult terms

Appendix 1 table 1. Overview of evaluated potentially difficult terms from the patient-friendly list

LLT	LLT code	Your opinion		For other people		Suggestions for improvement
		Unclear	Clear	Unclear	Clear	
Abdominal abscess	10060921	x		x		
Abnormal liver function tests	10000158	x		x		Wouldn't know how you know this without a test
Accidental overdose	10000381		x	x		Taken too many by mistake
Acute myeloid leukaemia	10000880	x		x		
ADHD	10064104		x		x	
Agoraphobia	10001502		x		x	
Alcohol interaction	10001597		x	x		Had alcohol with medication
Alertness decreased	10049875		x		x	
Application site papules	10049043	x		x		
Atrial flutter	10003662	x		x		Heart flutter/palpitations
Auditory hallucinations	10003785		x		x	
Axillary pain	10048750	x		x		
Blood glucose increased	10005557		x		x	
Blood sugar decreased	10005808	x		x		Don't know how I would know blood sugar decreased
Bone density decreased	10049470		x	x		
Bone fragile	10005966		x		x	
Bone loss	10065687		x		x	
Breakthrough pain	10064556	x		x		
Candida infection	10074170	x		x		
Cardiopulmonary failure	10051093	x		x		Could be indigestion?
Cholesterol levels raised	10008663		x		x	
Clavicle fracture	10009245	x		x		
Clot blood	10009667	x		x		
Clotting disorder	10064732		x		x	
Condition aggravated	10010264		x	x		
Deafness unilateral	10048812	x		x		
Deep vein thrombosis	10051055	x		x		Never having had something like this I'm not sure I would distinguish it with cramp?

Dermatitis	10012431		x		x	
Diabetic neuropathy	10012680	x			x	
Diverticulitis	10013538		x		x	
Drug effect decreased	10013678		x			x
Ectopic pregnancy	10014166	x			x	
Edema	10014210	x			x	
Endometriosis	10014778	x			x	
Esophagitis	10015461	x			x	
Facial bones fracture	10016042		x		x	Face bone broken
Fatty liver	10016261	x			x	
Femur fracture	10016454	x			x	
Fistula	10016717	x			x	
Gastric disorder	10056819		x		x	
Gastric perforation	10017815	x			x	
GERD	10018203	x			x	
Grand mal convulsion	10018659	x			x	
Guillain-Barre syndrome	10018767	x			x	
Hand deformity	10061194		x			x
Hepatitis C	10019744	x			x	
Hypertension	10020772		x		x	
Hyperthyroidism	10020850	x			x	
Hyperventilation	10020910		x		x	
Impaired liver function	10021520		x			x
Increased urinary frequency	10021692		x		x	Older people more likely to be aware of this
Infusion site swelling	10053505		x			x
Injection site inflammation	10022078		x			x
Iron low	10022982		x		x	Only know this following a blood test
Laceration	10023572	x				
Libido decreased	10024419		x			x
Lip disorder	10048470		x			x
Lumbar pain	10024998		x			x
Lung cancer metastatic	10050017	x			x	
Lymphedema	10025233	x			x	
Lymphoedema	10025282	x			x	
Macular degeneration	10025409	x			x	

Metastases to lung	10027458	x		x	
Metastases to lymph nodes	10027459	x		x	Wouldn't know symptoms of this
Metastasis	10062194	x		x	
Movements abnormal	10028039		x		
Mucous membrane disorder	10028133	x		x	
Multiple myeloma	10028228	x		x	
Myalgic encephalomyelitis	10028414	x		x	
Myelodysplastic syndrome	10028533	x		x	
Necrosis	10028851	x		x	
Nerve damage	10029177	x		x	Again wouldn't be able to distinguish this from bruising?
Neuropathy	10029328	x		x	
Nicotine addiction	10056478		x		x
Oedema	10030095	x		x	
Oesophageal pain	10030180		x		x
Osteoporosis	10031282		x		x
Patella fracture	10034122		x	x	Broken kneecap
Pelvic inflammatory disease	10034254	x		x	Not sure of symptoms
Pharyngitis	10034835	x		x	
Polycystic ovaries	10036049	x		x	
Polyp	10061529	x		x	
Postmenopausal bleeding	10036399		x		x
Product quality issue	10069327	x		x	
Product size issue	10069249	x		x	
Product taste abnormal	10069227		x		x
Psychosis	10037234	x		x	
Radius fracture	10037802	x		x	
Raynaud's syndrome	10037914	x		x	Would have to look it up on google
Shoulder bursitis	10040611	x		x	
Skin abrasion	10064990		x		x
Skin depigmentation	10040825		x		x
Skin pigmentation	10040910		x		x
Soft tissue disorder	10061366		x	x	
Sore oesophagus	10041365	x		x	
Substance abuse	10066169		x		x
Tenderness	10043224		x		x
Tendinitis	10043232	x		x	Could be other causes

Thrombosis leg	10043623		x	x		Swollen leg
Tibia fracture	10043827	x			x	
Type 1 diabetes mellitus	10067584		x			x
Underdose	10057362	x			x	
Unilateral vision loss	10059679		x	x		
Urinary retention	10046555		x			x
Urticaria	10046735		x	x		
Uterine prolapse	10046814	x			x	
Vaccination site inflammation	10068878		x			x
Venous thrombosis	10047249		x	x		I might know but could confuse it with something else...
Visual hallucinations	10047570		x			x
Vulvovaginal pain	10069055	x			x	
Weakness left or right side	10047866		x			x
Whitlow	10059856	x			x	
Wound healing delayed	10048036		x			x
Writing impaired	10048053		x			X
LLT = Lowest level term						

7.2 Overview of evaluated probably understandable terms

Appendix 1 table 2. Overview of evaluated probably understandable terms from the patient-friendly list

LLT	LLT code	Your opinion		For other people		Suggestions for improvement
		Unclear	Clear	Unclear	Clear	
Scoliosis	10039722	x		x		
Shingles	10040555		x		x	
Ache	10000424		x		x	
Cold feet	10009859		x		x	
Dizziness	10013573		x		x	
Eye burns	10015911	x		x		
Flu	10016790		x		x	
Hand rash	10019117		x		x	
Increased tendency to bruise	10021688		x		X	
LLT = Lowest level term						

8 Appendix 2. LLTs in ADR reports – Study 3

Appendix 2 table 1. Overview of LLTs in the ADR reports by those using the patient-friendly terms list or not

LLT	Using the patient-friendly terms list			Potentially difficult term (1=yes; 0=no)
	No	Yes	Total	
Abdominal bloating	3	2	5	0
Abdominal colic	1	0	1	0
Abdominal cramps	3	1	4	0
Abdominal discomfort	1	0	1	0
Abdominal disorder	1	0	1	0
Abdominal pain	13	3	16	0
Abnormal behaviour	3	1	4	0
Abnormal breathing	1	0	1	0
Abnormal chest sounds	1	0	1	0
Abnormal dreams	3	0	3	0
Abnormal faeces	1	0	1	0
Abnormal liver function tests	1	0	1	1
Abnormal loss of weight	2	1	3	0
Abnormal physical sensation	1	0	1	0
Abnormal stools	2	0	2	0
Abnormal thinking	1	0	1	0
Abnormal weight gain	15	0	15	0
Accidental overdose	1	0	1	1
Accidental underdose	1	0	1	0
Ache	5	1	6	0
Ache stomach	2	0	2	0
Aches & pains in legs	1	0	1	0
Achilles tendon discomfort	2	0	2	0
Achilles tendon pain	0	1	1	0
Aching in limb	1	0	1	0
Aching joints	1	0	1	0
Acid reflux (esophageal)	1	0	1	0
Acid reflux (oesophageal)	4	0	4	0
Acne	3	1	4	0
Acute kidney injury	0	1	1	0
Acute massive pulmonary embolism	1	0	1	0
Addiction	1	0	1	0
Addisonian crisis	1	0	1	0
Adhesive plaster sensitivity	1	0	1	0
After taste	1	1	2	0
Aggression	3	0	3	0
Aggressiveness	1	0	1	0
Agitated	3	1	4	0
Agitation	7	0	7	0
Air hunger	1	0	1	0
Akathisia	3	1	4	0

Alanine aminotransferase increased	1	0	1	0
Alcohol abuse	1	0	1	0
Alcohol craving	1	0	1	0
Alcohol intolerance	3	0	3	0
Alcohol tolerance lowered	1	0	1	0
Alkaline phosphatase increased	1	0	1	0
Allergic purpura	1	0	1	0
Allergic rash	2	1	3	0
Allergic reaction	8	1	9	0
Allergic reaction to excipient	2	0	2	0
Allergic rhinitis	2	0	2	0
Alopecia	1	0	1	0
Altered hormone level	1	0	1	0
Altered saliva	1	0	1	0
Amenorrhea	1	0	1	0
Amnesia	1	0	1	0
Anal bleeding	0	2	2	0
Anal discomfort	1	0	1	0
Anal fissure	1	0	1	0
Anal inflammation	2	0	2	0
Anal pain	0	1	1	0
Anal pruritus	1	0	1	0
Anaphylactic reaction	0	1	1	1
Anger	3	2	5	0
Angina attack	1	0	1	0
Angina pectoris	1	0	1	0
Anhedonia	3	0	3	0
Ankle oedema	1	0	1	0
Ankle swelling	2	0	2	0
Anorgasmia	1	1	2	0
Anosmia	1	0	1	0
Anxiety	23	6	29	0
Anxiety aggravated	3	0	3	0
Anxiety attack	0	1	1	0
Anxiety depression	1	0	1	0
Anxious mood	1	1	2	0
Appetite lost	21	5	26	0
Application site bleeding	1	0	1	0
Application site blister	1	0	1	0
Application site burn	1	0	1	0
Application site burning	2	0	2	0
Application site discharge	1	0	1	0
Application site irritation	1	0	1	0
Application site itching	0	1	1	0
Application site pain	2	0	2	0
Application site peeling	1	0	1	0
Application site redness	1	0	1	0
Argumentativeness	1	0	1	0
Arm discomfort	1	0	1	0
Arrhythmia	0	1	1	0

115632 – WEB-RADR – D3B.5

Arthralgia	3	0	3	0
Arthritic-like pain	1	0	1	0
Arthritis	1	0	1	0
Asthma aggravated	2	1	3	0
Asthmatic attack	1	0	1	0
Atrial fibrillation	2	0	2	0
Auditory and visual hallucinations	1	0	1	0
Auditory hallucinations	1	0	1	1
Aura	1	0	1	1
Avoidant personality	1	0	1	0
Back ache	4	0	4	0
Back arched backward	1	0	1	0
Back muscle spasms	1	0	1	0
Back pain	8	1	9	0
Back pain (with radiation)	1	0	1	0
Backache	1	1	2	0
Bacterial infection	0	1	1	0
Bacterial vaginosis	1	0	1	0
Bad breath	1	0	1	0
Bad dreams	1	0	1	0
Bad mood	1	0	1	0
Balance disorder	2	0	2	0
Balanitis	1	0	1	0
Behavior disorder	1	0	1	0
Behaviour abnormal	1	0	1	0
Belching	1	0	1	0
Bile duct stricture	1	0	1	0
Bilious vomiting	1	0	1	0
Binge eating	1	0	1	0
Bipolar disorder	1	0	1	0
Black stools	1	0	1	0
Blacked out	2	0	2	0
Blackout	3	0	3	0
Bladder dilatation	1	0	1	0
Bladder infection	1	1	2	0
Bladder pain	1	0	1	0
Bleeding	5	1	6	0
Bleeding menstrual heavy	1	0	1	0
Bleeding nose	0	1	1	0
Bleeding time prolonged	1	0	1	0
Blepharospasm	0	1	1	0
Blindness temporary	1	0	1	0
Blister	1	0	1	0
Blistering	3	0	3	0
Blistering of mouth	1	0	1	0
Blisters	3	0	3	0
Blistery rash	2	0	2	0
Bloated feeling	2	0	2	0
Bloating	9	0	9	0
Blood cholesterol increased	1	0	1	0

115632 – WEB-RADR – D3B.5

Blood disorder	1	0	1	0
Blood in stool	1	0	1	0
Blood in urine	3	1	4	0
Blood pressure decreased	1	0	1	0
Blood pressure high	1	1	2	0
Blood pressure increased	5	0	5	0
Blood pressure low	2	0	2	0
Blood pressure systolic low	1	0	1	0
Blood sugar decreased	2	0	2	1
Blood test abnormal	1	0	1	0
Blood thyroid stimulating hormone increase	1	0	1	0
Bloodshot eye	3	0	3	0
Bloody diarrhoea	1	0	1	0
Bloody discharge	1	0	1	1
Bloody stool	1	0	1	0
Blotchy	1	0	1	0
Blotchy rash	2	0	2	0
Blurred vision	9	3	12	0
Body odour	0	1	1	0
Body temperature decreased	1	0	1	0
Body temperature increased	4	0	4	0
Boil	1	1	2	0
Bone pain	3	0	3	0
Bowel incontinence	2	0	2	0
Bowel obstruction	1	0	1	0
Brain damage	1	0	1	0
Brain swelling	1	0	1	0
Breast discharge	2	0	2	0
Breast enlargement female	1	0	1	0
Breast enlargement male	0	2	2	0
Breast lump (benign)	1	0	1	0
Breathing arrested	1	0	1	0
Breathing difficult	1	0	1	0
Breathing shallow	1	0	1	0
Breathlessness	10	0	10	0
Brittle nails	1	1	2	0
Broken nails	2	0	2	0
Bronchiectasis	1	0	1	0
Brown urine	1	0	1	0
Bruise	1	0	1	0
Bruising	1	1	2	0
Bruising of face	0	1	1	0
Bruxism	1	0	1	0
Burning in throat	5	1	6	0
Burning mouth	2	0	2	0
Burning oral sensation	1	0	1	0
Burning sensation	17	0	17	0
Burning sensation in eye	1	0	1	0
Burning sensation skin	1	0	1	0

Burning skin	2	1	3	0
Burning tongue	3	1	4	0
Burping	0	1	1	0
Bursitis of knee	1	0	1	0
Buttock pain	0	1	1	0
Calcium deposits	1	0	1	0
Calf discomfort	1	0	1	0
Calf pain	1	0	1	0
Canker sores oral	1	0	1	0
Cardiac arrest	1	0	1	0
Cardiac arrhythmia	2	0	2	0
Cardiac pain	1	0	1	0
Carpal tunnel syndrome	1	0	1	0
Catarrh	1	0	1	0
Central pain syndrome	1	0	1	0
Cerebrovascular accident	1	0	1	0
Change in bowel habits	1	0	1	0
Chest burning pain of	1	0	1	0
Chest discomfort	2	0	2	0
Chest hot feeling of	1	0	1	0
Chest infection	2	0	2	0
Chest pain	20	3	23	0
Chest pain - cardiac	1	0	1	0
Chest pressure	1	0	1	0
Chest pressure sensation of	1	0	1	0
Chest tightness	2	3	5	0
Chills	4	0	4	0
Choking sensation	1	0	1	0
Cholesterol high	1	0	1	0
Chronic fatigue	2	3	5	0
Chronic fatigue syndrome	1	0	1	0
Chronic heartburn	2	0	2	0
Chronic wheezing	1	0	1	0
Clamminess	1	0	1	0
Clammy	1	1	2	0
Claustrophobia	1	0	1	0
Clot blood	1	0	1	1
Cloudy urine	1	0	1	0
Cloudy vision	0	1	1	0
Clumsiness	2	0	2	0
Cluster headaches	1	0	1	0
Coffee ground vomiting	1	0	1	0
Cognitive deterioration	1	0	1	0
Cognitive disorder	1	0	1	0
Cognitive impairment	2	1	3	1
Cold	4	0	4	0
Cold sweat	0	1	1	0
Cold symptoms	1	0	1	0
Coldness	1	0	1	0
Concentration ability impaired	1	0	1	0

115632 – WEB-RADR – D3B.5

Concentration impaired	4	0	4	0
Concentration loss	6	2	8	0
Condition aggravated	17	0	17	1
Confusion	12	2	14	0
Conjunctival concretion	1	0	1	0
Constipation	14	7	21	0
Constipation chronic	1	0	1	0
Contraction skeletal muscle	1	0	1	0
Contraindicated drug administered	1	0	1	0
Contraindicated drug prescribed	2	0	2	0
Convulsion	0	1	1	0
Cough	6	0	6	0
Cough aggravated	1	0	1	0
Coughing	5	1	6	0
Cramp of limb	0	1	1	0
Cramps	3	0	3	0
Cramps in legs	1	0	1	0
Crawling sensation of skin	2	0	2	0
Crying	2	0	2	0
Crying abnormal	2	0	2	0
Cyst	1	0	1	0
Cystic acne	1	0	1	0
Cystic adenomatoid malformation	1	0	1	0
Cystitis-like symptom	1	0	1	0
Dark circles under eyes	1	0	1	0
Daytime sleepiness	3	2	5	0
Deafness	1	0	1	0
Decreased appetite	1	0	1	0
Decreased muscle tone	1	0	1	0
Deep vein thrombosis	1	0	1	1
Defecation desire	1	0	1	0
Dehydration	2	2	4	0
Delayed period	2	0	2	0
Deliberate self-harm	2	0	2	0
Delusion	1	1	2	0
Delusions	1	0	1	0
Dental cavity	1	0	1	0
Depressed mood	1	0	1	0
Depression	25	3	28	0
Depression aggravated	3	0	3	0
Depressive state	1	0	1	0
Detached retina	0	1	1	0
Detachment emotional	1	0	1	0
Diabetic ketoacidosis	0	1	1	0
Diarrhea	4	5	9	0
Diarrhoea	39	15	54	0
Diarrhoea aggravated	2	0	2	0
Difficulty breathing	17	3	20	0
Difficulty focusing eyes	5	1	6	0
Difficulty sleeping	9	3	12	0

115632 – WEB-RADR – D3B.5

Difficulty thinking	1	0	1	0
Digestion impaired	1	0	1	0
Dilatation of stomach	1	0	1	0
Dilated pupils	1	0	1	0
Diminished sense of smell	1	0	1	0
Discoloration urine	2	0	2	0
Discoloured stools	1	0	1	0
Discomfort	3	0	3	0
Discomfort in joints	1	0	1	0
Disorientated	1	1	2	0
Disorientation	3	0	3	0
Distended abdomen	1	0	1	0
Disturbance in attention	1	0	1	0
Diverticulitis	1	0	1	1
Dizziness	40	14	54	0
Dizziness aggravated	1	0	1	0
Dizziness on standing up	0	2	2	0
Dizzy	6	1	7	0
Dizzy spells	2	2	4	0
Double vision	0	1	1	0
Dream delirium	1	0	1	0
Drowsiness	8	3	11	0
Drug administration duration too long	1	0	1	0
Drug administration error	1	0	1	0
Drug allergy	1	0	1	0
Drug dose prescribing error	1	0	1	0
Drug effect delayed	1	0	1	1
Drug ineffective	18	0	18	0
Drug interaction	5	0	5	0
Drug intolerance	1	0	1	0
Drug monitoring procedure not performed	1	0	1	0
Drug overdose	1	0	1	0
Drug schedule prescribing error	1	0	1	0
Drug withdrawal syndrome	4	0	4	0
Dry cough	0	1	1	0
Dry eyes	2	3	5	0
Dry hair	1	0	1	0
Dry heaves	0	1	1	0
Dry lips	1	0	1	0
Dry mouth	12	6	18	0
Dry nose	1	0	1	0
Dry skin	6	2	8	0
Dry throat	5	0	5	0
Dysgeusia	6	0	6	0
Dyspepsia	1	0	1	0
Dyspnoea	1	0	1	0
Dyspnoea exertional	1	0	1	0
Ear infection	1	0	1	0
Ear popping sensation	1	0	1	0

Ear ringing	1	0	1	0
Ectopic pregnancy	1	0	1	1
Eczema	2	0	2	0
Eczema aggravated	1	0	1	0
Electric shock sensation	4	1	5	0
Emotional disorder	2	0	2	0
Emotional distress	1	0	1	0
Encephalopathy	1	0	1	0
Erectile dysfunction	4	1	5	0
Erythema	4	0	4	0
Erythematous rash	6	0	6	0
Erythropapular rash	1	0	1	0
Esophageal reflux	1	0	1	0
Euphoric mood	0	1	1	0
Exacerbation of asthma	1	0	1	0
Excess sweating	3	4	7	0
Excessive daytime sleepiness	1	0	1	0
Excessive flatulence	1	0	1	0
Excessive menstruation	1	0	1	0
Exertional dyspnoea	1	0	1	0
Exhaustion	10	1	11	0
External genitalia inflammation	1	0	1	0
Eye inflamed	1	0	1	0
Eye inflammation	1	0	1	0
Eye pain	3	1	4	0
Eye painful red	1	0	1	0
Eye red	1	0	1	0
Eye swelling	1	0	1	0
Eyes heavy feeling of	1	0	1	0
Eyes red	1	0	1	0
Eyes rolling	1	1	2	0
Eyes swollen	1	0	1	0
Facial pain	1	0	1	0
Facial spasm	2	0	2	0
Facial swelling	4	1	5	0
Fainting	4	1	5	0
Fall	1	0	1	0
Fallopian tube disorder	1	0	1	0
Fatigue	27	1	28	0
Fatigue extreme	2	0	2	0
Fatty liver	1	0	1	1
Fear	1	0	1	0
Feeling abnormal	5	0	5	0
Feeling anxious	3	1	4	0
Feeling cold	2	0	2	0
Feeling detached	4	0	4	0
Feeling down	1	0	1	0
Feeling drunk	1	0	1	0
Feeling hot	7	0	7	0
Feeling hot and cold	4	0	4	0

Feeling jittery	1	0	1	0
Feeling of fullness in abdomen	1	0	1	0
Feeling of residual urine	1	0	1	0
Feeling of total lack of energy	2	1	3	0
Feeling sick	8	4	12	0
Feeling unwell	13	0	13	0
Feelings of weakness	2	0	2	0
Felt faint	4	0	4	0
Felt like a zombie	2	0	2	0
Femur fracture	1	0	1	1
Ferritin increased	1	0	1	0
Fever	16	2	18	0
Fever chills	2	1	3	0
Finger deformity	1	0	1	1
Fit (in known epileptic)	1	0	1	0
Flaking skin	2	0	2	0
Flashing vision	2	0	2	0
Flatulence	4	0	4	0
Floaters in eye	1	0	1	0
Floppy infant	2	0	2	0
Flu like symptoms	5	1	6	0
Flu symptoms	2	0	2	0
Flu-like symptoms	3	0	3	0
Flushing	2	0	2	0
Foggy feeling in head	10	1	11	0
Folic acid decreased	1	0	1	0
Fontanelle bulging	1	0	1	0
Food allergy	1	0	1	0
Food intolerance	2	0	2	0
Foot pain	2	0	2	0
Forehead headache	1	0	1	0
Foreign body in nose	1	0	1	0
Forgetfulness	2	0	2	0
Fractured compression T8	1	0	1	0
Frequent bowel movements	2	0	2	0
Frequent headaches	8	3	11	0
Fungal infection	2	1	3	0
Fuzzy	1	0	1	0
Fuzzy head	5	2	7	0
Gallbladder disorder	1	0	1	0
Gas in stomach	1	0	1	0
Gas incontinence	1	0	1	0
Gastric acid decreased	1	0	1	0
Gastrointestinal discomforts	2	1	3	0
Gastrointestinal inflammation	1	0	1	0
Gastrointestinal pain	2	0	2	0
Gastroparesis	1	0	1	0
General body pain	1	0	1	0
Generalised aching	1	0	1	0
Generalised erythema	1	0	1	0

115632 – WEB-RADR – D3B.5

Generalised itching	5	0	5	0
Generalised rash	1	0	1	0
Generalised urticaria	1	0	1	0
Generalized urticarial rasg	1	0	1	0
Generally unwell	5	0	5	0
Genital burning sensation	1	0	1	0
Genital discomfort	2	0	2	0
Genital disorder male	2	0	2	0
Genital itching	4	1	5	0
Genital itching female	1	0	1	0
Genital swelling	1	0	1	0
Glandular fever	1	0	1	0
Globus feeling in pharynx	1	0	1	0
Glomerular filtration rate decreased	1	0	1	0
Gluten intolerance	1	0	1	0
Gout attack	1	0	1	0
Gritty eyes	1	0	1	0
Groin pain	0	1	1	0
Gum bleeding	1	0	1	0
Gum disorder	1	0	1	0
Gum recession	1	0	1	0
Gum swelling	1	0	1	0
Gynaecomastia	1	0	1	0
Haemoglobin low	1	0	1	0
Haemorrhagic stroke	1	0	1	0
Haemorrhoids	1	0	1	0
Haemorrhoids aggravated	1	0	1	0
Hair colour graying	1	0	1	0
Hair discolouration	1	0	1	0
Hair loss	9	8	17	0
Hair texture abnormal	1	0	1	0
Hair thinning	2	3	5	0
Hallucination	1	0	1	0
Hallucinations	4	2	6	0
Hand pain	1	0	1	0
Hand swelling	1	0	1	0
Hand-foot-and-mouth disease	1	0	1	0
Hands weakness of	1	0	1	0
Head pain	7	0	7	0
Head pressure	1	0	1	0
Head throbbing	0	1	1	0
Headache	69	8	77	0
Headache dull	2	0	2	0
Healing delayed	1	0	1	0
Hearing impaired	2	0	2	0
Hearing loss	0	1	1	0
Hearing loss bilateral	0	1	1	1
Heart attack	1	0	1	0
Heart disorder	1	0	1	0
Heart fluttering	1	0	1	0

115632 – WEB-RADR – D3B.5

Heart pounding	3	2	5	0
Heart racing	5	0	5	0
Heart rate high	3	0	3	0
Heart rate increased	8	0	8	0
Heart rate irregular	2	1	3	0
Heartbeats irregular	0	1	1	0
Heartbeats skipped	0	1	1	0
Heartburn	7	6	13	0
Heat intolerance	2	0	2	0
Heat sensitivity	1	0	1	0
Heaviness in limbs	1	0	1	0
Heavy periods	2	0	2	0
Heavy sweating	1	0	1	0
Hemiparesis	1	0	1	0
Henoch-Schonlein purpura nephritis	1	0	1	0
High temperature	14	3	17	0
Hives	4	2	6	0
Hoarse voice	1	0	1	0
Hoarseness	1	0	1	0
Hoarseness of voice	1	0	1	0
Hostility	1	0	1	0
Hot flashes	1	0	1	0
Hot flushes	4	1	5	0
Hunger	2	0	2	0
Hunger abnormal	1	0	1	0
Hyperaesthesia skin	1	0	1	0
Hypersensitivity	2	0	2	0
Hypersexuality	1	0	1	0
Hypersomnia	2	0	2	0
Hypertension	1	0	1	1
Hyperthyroidism	0	1	1	1
Hypoglycaemia	1	0	1	1
Hypoglycaemic episode	1	0	1	0
Hypohidrosis	1	0	1	0
Hypomania	1	0	1	0
Hyponatraemia	1	0	1	0
Hypotension	1	0	1	1
Hypothyroidism	5	1	6	1
Hysteria	1	0	1	0
Idiopathic pulmonary fibrosis	1	0	1	0
Ill feeling	2	0	2	0
Impaired liver function	1	0	1	1
Inability to orgasm	1	3	4	0
Incorrect storage of drug	1	0	1	0
Increased appetite	1	0	1	0
Increased bowel frequency	1	1	2	0
Increased stool frequency	1	0	1	0
Increased thirst	1	0	1	0
Increased urinary frequency	3	0	3	1
Indigestion	3	0	3	0

Infection susceptibility increased	1	0	1	0
Infection via vaccine	2	1	3	0
Inflammation localised	2	0	2	0
Ingrown hair	1	0	1	0
Inhibitory drug interaction	2	0	2	0
Injection site abscess	1	0	1	0
Injection site discharge	1	0	1	0
Injection site fat necrosis	1	0	1	0
Injection site infection	1	0	1	0
Injection site numbness	1	0	1	0
INR increased	1	0	1	0
Insomnia	25	8	33	0
Intentional overdose	1	0	1	0
Intentional self-injury	1	0	1	0
Intermittent fever	1	0	1	0
Intestinal bacteria flora disturbance	1	0	1	0
Intracranial hypertension	1	0	1	0
Intrusive thoughts	3	0	3	0
Irregular menstruation	1	0	1	0
Irregular periods	1	0	1	0
Irregular pulse	1	0	1	0
Irritability	6	1	7	0
Irritable	6	2	8	0
Irritable bowel syndrome	1	0	1	0
Irritable bowel syndrome aggravated	2	0	2	0
Itch	1	0	1	0
Itching	19	0	19	0
Itching all over	5	2	7	0
Itching both hands	3	0	3	0
Itching eyes	1	0	1	0
Itchy	9	2	11	0
Itchy eyes	1	0	1	0
Itchy rash	6	2	8	0
Itchy scalp	3	0	3	0
Itchy skin	7	1	8	0
Jaundice	1	1	2	0
Jaw pain	1	0	1	0
Jaw stiffness	1	0	1	0
Jerkiness	2	0	2	0
Joint ache	3	0	3	0
Joint crepitation	1	0	1	0
Joint disorder	1	0	1	0
Joint inflammation	1	0	1	0
Joint pain	22	2	24	0
Joint stiffness	3	0	3	0
Joint swelling	3	0	3	0
Keratosis pilaris	1	0	1	0
Kidney pain	2	0	2	0
Knee arthritis	1	0	1	0
Knee pain	3	0	3	0

115632 – WEB-RADR – D3B.5

Knee swelling	1	0	1	0
Lack of coordination	2	0	2	0
Lack of drug effect	4	0	4	0
Lack of motivation	5	0	5	0
Lack of vaccination site rotation	1	0	1	0
Lactose intolerance	1	0	1	0
Late period	0	1	1	0
Left bundle branch block	1	0	1	0
Leg cramps	4	0	4	0
Leg pain	4	1	5	0
Lethargic	3	1	4	0
Lethargy	7	3	10	0
Libido decreased	3	0	3	1
Libido increased	1	0	1	1
Light periods	2	0	2	0
Light sensitivity to eye	1	2	3	0
Light sleep	1	0	1	0
Light-headed	2	0	2	0
Lightheadedness	5	0	5	0
Limb discomfort	1	0	1	0
Lip pain	2	0	2	0
Lip swelling	3	0	3	0
Listless	0	2	2	0
Liver inflammation	1	0	1	0
Liver pain	1	0	1	0
Local swelling	3	0	3	0
Localised erythema	3	0	3	0
Localised itching	7	0	7	0
Localised muscle pain	2	0	2	0
Localised numbness	1	0	1	0
Localised rash	1	0	1	0
Localised tingling	4	0	4	0
Loose bowel	1	0	1	0
Loose bowels	2	0	2	0
Loose stools	2	2	4	0
Loss of all pleasure	1	0	1	0
Loss of confidence	1	0	1	0
Loss of energy	2	0	2	0
Loss of eyelashes	1	0	1	0
Loss of interest	2	0	2	0
Loss of libido	7	0	7	1
Loss of memory	1	0	1	0
Loss of sensation	2	1	3	0
Loss of smell	1	0	1	0
Loss of taste	4	0	4	0
Loss of vision	2	0	2	0
Loss of voice	1	0	1	0
Low back pain	7	0	7	0
Low blood pressure	2	1	3	0
Low mood	5	1	6	0

115632 – WEB-RADR – D3B.5

Lower abdominal pain	2	0	2	0
Lump feeling in throat	2	0	2	0
Lung fibrosis	1	0	1	0
Lung irritation	2	0	2	0
Lymphadenopathy	1	0	1	0
Macrocytosis	0	1	1	0
Maculopapular rash	1	0	1	0
Madarosis	1	0	1	0
Major depression	1	0	1	0
Malaise	2	0	2	0
Male sexual dysfunction	1	0	1	0
Mania	1	0	1	0
Manic	1	0	1	0
Mass	1	0	1	0
Measles-like rash	2	0	2	0
Meibomian gland obstruction	1	0	1	0
Memory impaired	3	0	3	0
Memory impairment	4	0	4	0
Memory loss	3	1	4	0
Menstruation increased	1	0	1	0
Menstruation prolonged	2	0	2	0
Mental concentration difficult	2	0	2	0
Mental fatigue	1	0	1	0
Mental impairment	1	0	1	0
Mental state abnormal	1	0	1	0
Mental status changes	0	1	1	0
Metabolic acidosis	1	0	1	0
Migraine	10	3	13	0
Migraine headache	2	1	3	0
Migraine with aura	2	0	2	1
Mineral deficiency	1	0	1	0
Miscarriage	1	0	1	0
Mood altered	1	0	1	0
Mood change	4	1	5	0
Mood swings	7	2	9	0
Motion sickness	1	0	1	0
Mouth movement impaired	1	0	1	0
Mouth ulcer	2	0	2	0
Mouth ulceration	2	0	2	1
Movements involuntary	1	0	1	1
Mucus discharge	1	0	1	0
Multiple allergies	1	0	1	0
Muscle ache	10	2	12	0
Muscle cramps	1	0	1	0
Muscle fatigue	1	1	2	0
Muscle pain	15	2	17	0
Muscle spasm	1	1	2	0
Muscle spasms	2	0	2	0
Muscle tightness	3	0	3	0
Muscle twitching	4	1	5	0

Muscle wasting	1	0	1	1
Muscle weakness	7	0	7	0
Muscle weakness upper limb	1	0	1	0
Musculoskeletal pain	2	0	2	0
Myelitis	1	0	1	0
Nail ridging	1	0	1	0
Nappy rash	1	0	1	0
Nasal congestion	5	1	6	0
Nasal dryness	1	0	1	0
Nasal sinus congestion	1	0	1	0
Nasal stuffiness	1	1	2	0
Nausea	62	17	79	0
Nauseous	1	1	2	0
Near fainting	2	0	2	0
Neck pain	7	2	9	0
Neck swelling	3	0	3	0
Negative thoughts	3	0	3	0
Neonatal seizures	1	0	1	0
Nervous	1	0	1	0
Nervous breakdown	1	0	1	0
Nervous system disorder	1	0	1	0
Neuralgia	2	0	2	1
Neuropathy	2	0	2	1
Neurotic reaction	1	0	1	0
Night sweat	1	0	1	0
Night sweats	5	3	8	0
Night terrors	0	1	1	0
Nightmare	3	0	3	0
Nightmares	6	1	7	0
Nipple tenderness	1	0	1	0
Nocturia	0	1	1	0
Nocturnal headache	1	0	1	0
Nocturnal leg muscle cramps	0	1	1	1
Noises in head	1	0	1	0
Non-cardiac chest pain	0	1	1	0
Nose bleed	3	2	5	0
Nose bleeds	0	1	1	0
Nosebleed	2	0	2	0
Numbness	4	0	4	0
Numbness facial	1	0	1	0
Numbness in feet	1	0	1	0
Numbness in hand	1	0	1	0
Numbness in leg	1	0	1	0
Numbness localised	1	0	1	0
Numbness of tongue	1	1	2	0
Numbness throat	1	0	1	0
Obsessive thoughts	1	0	1	0
Obsessive-compulsive disorder	1	0	1	0
Occupational exposure to drug	1	0	1	0
Oesophageal acid reflux	1	0	1	0

Oesophageal obstruction	1	0	1	0
Oesophageal pain	1	0	1	1
Oesophageal reflux aggravated	1	0	1	0
Oesophageal spasm	1	0	1	0
Oesophageal ulcer	0	1	1	1
Oily skin	2	0	2	0
Olfactory hallucination	1	0	1	0
Optic nerve disorder	1	0	1	0
Oral infection	1	0	1	0
Oral mucosal eruption	1	0	1	0
Oral nodule	1	0	1	0
Oral thrush	3	0	3	1
Oromandibular dystonia	1	0	1	0
Osteopenia	1	0	1	0
Ovarian cyst	0	1	1	1
Oxygen saturation decreased	1	0	1	0
Pain	20	1	21	0
Pain aggravated	1	0	1	0
Pain ankle	1	0	1	0
Pain behind eyes	1	0	1	0
Pain burning	1	0	1	0
Pain in ankle	1	0	1	0
Pain in arm	5	0	5	0
Pain in extremity	3	0	3	0
Pain in eyes	1	0	1	0
Pain in fingers	1	0	1	0
Pain in hip	0	1	1	0
Pain in limb	4	0	4	0
Pain legs	2	0	2	0
Painful arm	2	0	2	0
Painful eye movement	1	0	1	0
Painful feet	1	0	1	0
Painful intercourse	0	1	1	0
Painful joints	1	0	1	0
Painful periods	2	0	2	0
Painful urination	1	0	1	0
Pale	1	0	1	0
Palpitations	15	3	18	0
Pancreatic enzyme abnormality	1	0	1	0
Pancreatic inflammation	1	0	1	0
Panic attack	1	0	1	0
Panic attacks	5	0	5	0
Papilloedema	1	0	1	0
Papular rash	2	0	2	0
Papule	6	0	6	0
Paraesthesia	3	0	3	0
Paralyzed	1	0	1	0
Paranoia	2	0	2	0
Partial seizures	0	1	1	0
Peak flow abnormal	1	0	1	0

Peeling mouth	1	0	1	0
Penile discharge	1	0	1	0
Penile pain	2	0	2	0
Penile size reduced	1	0	1	0
Penile swelling	2	0	2	0
Penile thrush	1	0	1	0
Perforation of prepyloric ulcer	1	0	1	0
Period pains	2	0	2	0
Periorbital swelling	1	0	1	0
Peripheral swelling	4	0	4	0
Persecutory delusion	1	0	1	0
Persistent cough	1	0	1	0
Persistent crying	1	1	2	0
Persistent vomiting	3	3	6	0
Personality change	1	0	1	0
Petechia	1	0	1	0
Petechial rash	1	0	1	0
Phimosis	1	0	1	0
Photosensitivity	1	0	1	0
Piles	1	0	1	0
Pins and needles	13	2	15	0
Pituitary disorder	1	0	1	0
Plantar fasciitis	1	0	1	1
Polycystic ovarian syndrome	1	0	1	0
Polymyalgia rheumatica	1	0	1	0
Poor sleep	1	0	1	0
Posterior vitreous detachment	1	0	1	0
Post-traumatic stress disorder	1	0	1	0
Postural orthostatic tachycardia syndrome	1	0	1	0
Potassium low	1	0	1	0
Pounding in head	1	0	1	0
Pre-existing condition improved	1	0	1	0
Premenstrual syndrome	2	0	2	0
Preparatory actions toward imminent suic	1	0	1	0
Prescribed underdose	1	0	1	0
Pressure in vagina	1	0	1	0
Product formulation issue	1	0	1	0
Product lot number issue	1	0	1	0
Product lot specific issue	2	0	2	0
Product quality issue	2	0	2	0
Product smell abnormal	1	0	1	0
Product substitution issue	13	0	13	0
Product substitution issue brand to brand	5	0	5	0
Product substitution issue brand to generic	6	0	6	0
Product substitution issue generic to generic	7	0	7	0

115632 – WEB-RADR – D3B.5

Productive cough	2	0	2	0
Prolactin high	1	0	1	0
Prolonged periods	1	0	1	0
Prostatic disorder	1	0	1	0
Prostatic pain	2	0	2	0
Pruritus	1	0	1	0
Pruritus aggravated	1	0	1	0
Psoriasis aggravated	1	0	1	0
Psychosis	1	1	2	1
Pulmonary embolism	1	0	1	1
Pulse irregular	1	0	1	0
Pulse rate decreased	1	0	1	0
Pulse rate increased	1	0	1	0
Pulse weak	1	0	1	0
Pyrexia	1	0	1	0
Rage	1	0	1	0
Raised rash	3	0	3	0
Rash	6	2	8	0
Rash aggravated	1	0	1	0
Rash all over	0	1	1	0
Rash both legs	1	0	1	0
Rash on face	2	0	2	0
Rash trunk	0	1	1	0
Raynaud's syndrome	1	0	1	1
Reaction to drug excipient	1	0	1	0
Reaction to drug excipients	4	0	4	0
Rectal bleeding	3	0	3	0
Rectal pain	0	1	1	0
Recurrent thrush	2	1	3	0
Red blotches	1	0	1	0
Redness	11	0	11	0
Redness facial	1	0	1	0
Redness generalised	1	0	1	0
Redness mouth	1	0	1	0
Redness of eyes	2	0	2	0
Redness of legs	1	0	1	0
Reflexes decreased	1	0	1	0
Renal disorder	1	0	1	0
Respiratory tract oedema	1	0	1	0
Restless	0	1	1	0
Restless legs	0	3	3	0
Restlessness	4	1	5	0
Retracted penis	1	0	1	0
Rhinorrhoea	1	0	1	0
ringing in ears	1	1	2	0
Rotavirus infection	1	0	1	0
Runny nose	5	0	5	0
Saliva decreased	1	0	1	0
Saliva increased	2	0	2	0
Saliva secretion increased	1	0	1	0

115632 – WEB-RADR – D3B.5

Scabbing	1	0	1	0
Scalp tenderness	1	0	1	0
Secretion discharge	2	0	2	0
Seizure	2	0	2	0
Seizures	0	1	1	0
Sensation of block in ear	1	0	1	0
Sensation of pressure in ear	1	0	1	0
Sensation of pressure in eye	1	0	1	0
Sensitivity of teeth	1	0	1	0
Serotonin syndrome	2	0	2	0
Sexual feeling decreased	1	0	1	0
Sexually inappropriate behaviour	1	0	1	0
Shaking	14	0	14	0
Shaking of hands	3	0	3	0
Shallow breathing	3	0	3	0
Shingles	3	0	3	0
Shivering	4	1	5	0
Shortness of breath	6	0	6	0
Short-term memory loss	2	0	2	0
Shoulder pain	5	1	6	0
Sickness	11	5	16	0
Silent migraine	1	0	1	0
Sinus headache	1	0	1	0
Sinus pressure	1	0	1	0
Sinusitis	1	0	1	0
Skin burning sensation	1	0	1	0
Skin discolouration	3	0	3	0
Skin erythema	1	0	1	0
Skin greasy	0	1	1	0
Skin irritation	6	1	7	0
Skin lesion	1	0	1	0
Skin mass	2	0	2	0
Skin peeling	3	0	3	0
Skin rash	2	1	3	0
Skin red	2	0	2	0
Skin scarring	1	0	1	0
Sleep apnea	1	0	1	0
Sleep apnoea	1	0	1	0
Sleep disturbance	8	0	8	0
Sleep excessive	4	0	4	0
Sleep restless	0	1	1	0
Sleep rhythm reversal	1	0	1	0
Sleepiness	6	0	6	0
Sleeplessness	2	1	3	0
Sleepy	1	0	1	0
Slowed thinking	2	0	2	0
Sluggishness	3	1	4	0
Slurred speech	2	0	2	0
Small intestinal bacterial overgrowth	1	0	1	0
Smell loss	1	0	1	0

Sneezing	3	0	3	0
Sodium low	1	0	1	0
Somnolence	1	0	1	0
Sore eyes	1	0	1	0
Sore gums	1	0	1	0
Sore mouth	2	0	2	0
Sore throat	11	3	14	0
Sore tongue	1	0	1	0
Sores mouth	1	0	1	0
Sound sensitivity increased	2	0	2	0
Spaced out	2	0	2	0
Speech disorder	5	0	5	0
Speech impairment NOS	2	0	2	0
Speech loss	2	0	2	0
Spinning sensation	1	0	1	0
Spontaneous bruising	1	0	1	0
Spotting between menses	0	1	1	0
Steroid withdrawal syndrome	1	0	1	0
Stiff fingers	1	0	1	0
Stiff neck	2	1	3	0
Stiffness	2	0	2	0
Stiffness shoulder	1	0	1	0
Stinging	2	0	2	0
Stinging mouth	1	0	1	0
Stinging sensation in eye	1	0	1	0
Stomach ache	6	1	7	0
Stomach burning sensation of	2	0	2	0
Stomach cramps	14	5	19	0
Stomach discomfort	4	1	5	0
Stomach pain	15	2	17	0
Stomach ulcer	1	0	1	0
Stomach upset	1	0	1	0
Stools hard	1	0	1	0
Strange smell sensation	1	0	1	0
Stress	1	0	1	0
Stress incontinence	1	0	1	0
Stroke	2	0	2	0
Subconjunctival haemorrhage	1	0	1	0
Sudden hearing loss	1	0	1	0
Sugar craving	1	0	1	0
Suicidal behaviour	2	0	2	0
Suicidal depression	6	3	9	0
Suicidal ideation	13	4	17	1
Suicide attempt	2	1	3	0
Sun sensitivity	2	1	3	0
Sunburn	1	0	1	0
Supraventricular tachycardia	1	0	1	0
Suspected counterfeit product	1	0	1	1
Swallowing difficult	3	0	3	0
Swallowing impaired	2	0	2	0

Swallowing painful	2	1	3	0
Sweat discolouration	1	0	1	0
Sweat odour abnormal	1	0	1	0
Sweating	15	1	16	0
Sweating decreased	1	0	1	0
Sweating increased	1	0	1	0
Swelling	2	0	2	0
Swelling (r) testicle	1	0	1	0
Swelling abdomen	1	0	1	0
Swelling arm	1	0	1	0
Swelling face	2	0	2	0
Swelling of eyelid	3	0	3	0
Swelling of face	2	0	2	0
Swelling of feet	2	0	2	0
Swelling of fingers	3	0	3	0
Swelling of L knee	1	0	1	0
Swelling of legs	4	0	4	0
Swelling of lips	1	0	1	0
Swelling of tongue	2	0	2	0
Swollen abdomen	1	0	1	0
Swollen ankles	3	0	3	0
Swollen arm	1	0	1	0
Swollen eyes	1	1	2	0
Swollen glands	1	0	1	0
Swollen lips	2	0	2	0
Swollen lymph nodes	1	0	1	0
Swollen mouth	1	0	1	0
Swollen thumb	1	0	1	0
Swollen tongue	1	1	2	0
Syncope	3	0	3	0
T4 increased	0	1	1	0
Tachycardia	1	0	1	0
Tardive dyskinesia	1	0	1	0
Taste bitter	1	1	2	0
Taste bitter-salty	2	0	2	0
Taste changed	1	0	1	0
Taste disturbance	3	0	3	0
Taste metallic	3	0	3	0
Tearfulness	0	1	1	0
Teeth chattering	1	0	1	0
Teeth clenching	0	2	2	0
Teeth grinding	1	1	2	0
Temperature regulation disorder	1	0	1	0
Tendency to bruise easily	1	0	1	0
Tendon rupture	1	0	1	0
Tendonitis	0	1	1	1
Tension headache	1	1	2	0
Testicular pain	2	1	3	0
Thick nasal mucus	1	0	1	0
Thinking abnormal	1	0	1	0

115632 – WEB-RADR – D3B.5

Thirst	2	0	2	0
Thirst decreased	1	0	1	0
Thoughts of self harm	1	0	1	0
Throat constriction	1	0	1	0
Throat irritation	2	0	2	0
Throat swelling	4	0	4	0
Thrush	1	1	2	1
Thrush vaginal	1	1	2	0
Tingling	3	0	3	0
Tingling feet/hands	2	0	2	0
Tingling lips	2	0	2	0
Tingling mouth	2	0	2	0
Tingling of extremity	1	0	1	0
Tingling sensation	1	1	2	0
Tingling skin	0	1	1	0
Tingling throat	1	1	2	0
Tingling tongue	1	1	2	0
Tinnitus	9	0	9	0
Tired all the time	2	5	7	0
Tiredness	26	2	28	0
Tongue black	1	0	1	0
Tongue pain	1	0	1	0
Tongue ulceration	1	0	1	0
Tongue white	2	0	2	0
Tooth coloured yellow	1	0	1	0
Tooth decay	1	0	1	0
Tooth pain	1	0	1	0
Total lung capacity decreased	1	0	1	0
Trembling	1	1	2	0
Tremor	3	2	5	0
Tremor of hands	1	0	1	0
Type 2 diabetes mellitus	1	0	1	1
Unable to eat	0	1	1	0
Unconscious	1	0	1	0
Uncontrollable crying	1	0	1	0
Unexpected therapeutic benefit	1	0	1	0
Unintentional weight loss	2	1	3	0
Unresponsive to stimuli	1	0	1	0
Unsteadiness	3	1	4	0
Upset stomach	6	2	8	0
Urinary frequency	2	0	2	0
Urinary incontinence	1	0	1	0
Urinary retention	1	0	1	1
Urinary tract infection	2	0	2	0
Urinary urgency	2	0	2	0
Urination difficulty	7	0	7	0
Urination frequency of	1	0	1	0
Urine colouring red	1	0	1	0
Urine discolouration	1	0	1	0
Urine flow decreased	1	0	1	0

115632 – WEB-RADR – D3B.5

Urine odour abnormal	3	1	4	0
Urine odour foul	1	0	1	0
Urine output decreased	1	0	1	0
Urticarial rash	2	0	2	0
Uterine fibroids aggravated	1	0	1	0
Uterine pain	1	0	1	0
Vaccination site bruising	1	0	1	0
Vaccination site erythema	3	0	3	0
Vaccination site induration	2	0	2	0
Vaccination site lump	3	0	3	0
Vaccination site pain	6	0	6	0
Vaccination site rash	1	0	1	0
Vaccination site swelling	5	0	5	0
Vaccination site tenderness	2	0	2	0
Vaccination site warmth	1	0	1	0
Vaginal bleeding	4	4	8	0
Vaginal discharge	0	1	1	0
Vaginal discomfort	1	0	1	0
Vaginal infection	1	0	1	0
Vaginal inflammation	1	0	1	0
Vaginal itching	1	0	1	0
Varicella-like rash	1	0	1	0
Vasculitis legs	1	0	1	0
Vegetative state chronic	1	0	1	0
Vein disorder	1	0	1	0
Vein pain	1	0	1	0
Ventricular contractions premature	1	0	1	0
Vertigo	6	1	7	0
Violence	1	0	1	0
Vision blurred	1	0	1	0
Vision loss	1	0	1	0
Visual acuity reduced	1	0	1	0
Visual disturbance	8	0	8	0
Visual flashes	1	0	1	0
Visual hallucinations	3	1	4	1
Visual impairment	3	0	3	0
Vitamin B12 decreased	1	0	1	0
Vivid dreams	1	0	1	0
Vocal cord dysfunction	1	0	1	0
Voice alteration	1	0	1	0
Voice lowered	1	0	1	0
Vomiting	18	11	29	0
Vomiting aggravated	1	0	1	0
Vomiting projectile	1	1	2	0
Warmness in eyes	1	0	1	0
Warts	1	0	1	0
Water retention	3	0	3	0
Watering eyes	1	0	1	0
Watery diarrhea	1	0	1	0
Watery diarrhoea	3	2	5	0

115632 – WEB-RADR – D3B.5

Weakness	10	0	10	0
Weakness generalised	1	0	1	0
Weakness left or right side	1	0	1	1
Weight loss	1	0	1	0
Wheeze	1	0	1	0
Wheezing	5	1	6	0
Wheezy	1	0	1	0
Wind	5	0	5	0
Withdrawal reaction	2	0	2	1
Withdrawal symptom	3	0	3	0
Word finding difficulty	1	0	1	0
Worsening of tinnitus	2	0	2	0
Wound healing delayed	1	0	1	1
Wound oozing	1	0	1	0
Wound secretion	1	0	1	0
Wound weeping	2	0	2	0
Wrist pain	0	1	1	0
Wrong directions typed on label	1	0	1	0
Yawning	1	1	2	0

LLT = Lowest Level Term