YELLOW CARD DATA
APPLICATION TO PHARMACOVIGILANCE EXPERT ADVISORY GROUP

Applicants must read the Access to Yellow Card Data Guidance Notes before completing this form. These notes give relevant advice on each individual question in the Access to Yellow Card Data application form, as well as the conditions of use which applicants will be contractually obliged to adhere to when using Yellow Card Data.

Undertakings by the MHRA in relation to information provided by applicants

The information submitted on this form will be considered by. The Pharmacovigilance Expert Advisory Group (PEAG). PEAG will provide independent advice on applications for access to Yellow Card data. Any personal data provided in an application will be used only for statistical analysis, management, planning and in the provision of services by the MHRA. In accordance with the Data Protection Act 1998, PEAG and the MHRA will respect the confidentiality of all personal information, but reserve the right to publish in an anonymous and unidentifiable form summary data about applications received (via the internet or in its annual report) for reference and audit purposes.

Yellow Card data requests fall into the following categories:

Category Ia – Anonymised aggregated adverse drug reaction (ADR) data in the format of interactive Drug Analysis Profiles (iDAPs). These contain complete listings of all suspected adverse drug reactions or side effects, which have been reported to the MHRA via the Yellow Card Scheme. These are freely available from our website at https://yellowcard.mhra.gov.uk/iDAP/

Category Ib – A list of data fields which exclude any information that can identify the patient and reporter and therefore can be released without the need for PEAG consideration. A list of all the data fields that can be provided is given on the next page. Details of your request should be sent to vigilanceservice@mhra.gov.uk

Category II – If you require more than the Ib data fields then your request will be classed as a category II request (see section D.2 for the list of category II data fields). Applicants should complete this form and then send to type2yellowcarddata@mhra.gov.uk

Please note there is no requirement to complete this form when requesting Category Ia or Ib data.

Category I releasable data fields (Category Ib data)

Category Ib data case details listed below are releasable under the Freedom of Information Act (FOIA) without consideration by the PEAG. These are known as Category Ib data. Provision of these data will depend on the number of cases held by the Agency. The MHRA will not release any data subset in which there are five or fewer cases per cell. This is necessary to prevent identification of patients and/or reporters. Where there are less than five cases per cell the data will be aggregated with adjacent cells. Any aggregation will be clearly marked on the dataset.

Data fields
Patient age categories
Patient sex
Suspect drug(s)
Dose of suspect drug(s)
Route of administration
Duration of treatment
Suspected adverse drug reaction(s)
Adverse drug reaction outcome(s)
Time to onset
Past medical history
Year of receipt

For PEAG use only: **Protocol Number:** ..... **Date submitted:**	**IMPORTANT** **If you have any queries, please contact The Yellow Card Data Application Secretariat:** type2yellowcarddata@mhra.gov.uk

Section A – Personal details

A.1: Principal applicant (full name, job title, organisation, address, e-mail address for correspondence regarding this protocol)

A.2: List of all co-applicants / collaborators (Please list the names, job title, organisation, address and email addresses of all collaborators)

Section B – Title and summary of the proposal

B.1: Title of proposal for use of Yellow Card data

B.2: Name and address of the department / institution / place at which the research / analysis will be conducted

B.3: Proposed start date Proposed duration (if known)

Section C – Use of other databases

C.1 Are you intending to use Yellow Card data in combination with another database or other data sources1 (local, national, international or personal data archive).

Yes ☐ No ☐

If yes, please specify

Section D – Details of proposal

D.1: Would your research involve contacting the reporter and/or patient via the MHRA?

Yes ☐ No ☐

If yes, please specify (Note you will need to include with your application any documentation to be provided to reporters/patients regarding the proposed research project (e.g. information sheets, invitations letters, consent forms)

D.2: The main data fields that are usually provided as Category II are listed below. Only tick the fields that you require to meet the needs of the study.

Data fields	**Yes**	**No**	**If yes give further details as necessary**
Patient age	☐	☐	
Patient gender	☐	☐	
Suspect drug(s)	☐	☐	
Dose of suspect drug(s)	☐	☐	
Route of administration	☐	☐	
Drug start / stop dates	☐	☐	
Indication for suspect drug	☐	☐	
Suspected adverse drug reaction(s)	☐	☐	
Reaction outcome	☐	☐	
Reaction start / stop dates	☐	☐	
Reaction details (including description of	☐	☐	

[1] For example GP, hospital, Health board, death, employee records

reaction as provided by the reporter, action taken with the suspect drug as a result of the reaction)			
Test results	☐	☐	
Past medical history	☐	☐	
Previous drug history	☐	☐	
If you require additional information which is not listed above, please provide details			
	Yes	**No**	**If yes, please give details**
D.3: Have you applied for or received ethical approval for your request? Please provide a copy of any ethics committee approval and the reference number.	☐	☐	
D.4: Is the proposal subject to any agreement with any academic, commercial or other organisations?	☐	☐	
D.5: Is the proposal likely to lead to any patentable or commercially exploitable results	☐	☐	
D.6: Do you consider that the consequences of your research may have implications for public health?	☐	☐	

Section E – Relevant applications and publications

	Yes	**No**	**If yes, please give details**
E.1: Have you used Yellow Card data previously?	☐	☐	
E.2: Is this application a resubmission of a previous application?	☐	☐	
E.3: Have you previously submitted other applications to PEAG or its predecessors, ISAC or the Interim Committee on Yellow Card Data?	☐	☐	

Section F – Security & confidentiality

F.1: Please confirm that you will abide by the principles of the DPA 2018 as detailed in the guidance notes on Applications for Access to Yellow Card Data

Yes ☐ No ☐

F.2: How long do you intend to retain Yellow Card data following completion of the study? If longer than 12 month, please provide justification.

F.3: Please confirm all Yellow Card data provided will be confidentially and securely held on networks/laptops and that data will be appropriately destroyed once the research has been completed. (Please refer back to the guidance notes for further details)

Yes ☐ No ☐

Section G – Publication

G.1: How do you intend to disseminate the findings and results of your proposal? Please specify

G.2: Please confirm that you will submit a summary describing the outcomes of the study irrespective of intention to publish. This includes any draft abstracts / papers / presentations or publications. These should be submitted at least four calendar weeks prior to submission. The MHRA will review for potential regulatory action that maybe necessary and provide consent for publication. Consent will be based upon correct interpretation of the data and ensuring anonymity of YC patients and reporters.

Yes ☐ No ☐

Section H – Relevant research history

H.1: All applicants (principal and co-applicants) who will have access to any Yellow card data must list a

brief summary of relevant research history. Any recent experience and/or publications which are of particular relevance to the current application should be highlighted (Maximum of 10 articles).

Section I – Supplementary Information

I.1: If you have any comments on this application form please provide feedback:

Section J – Undertakings by the applicant(s) in relation to the application

1. I confirm that I have read, understood and agreed to comply with the Data Protection Statement and the Guidance Notes on Applications for Access to Yellow Card Data (see annex B).
2. I agree to use the data only for the intended purpose for which access was granted.
3. I will submit in writing any change to the proposed research methodology as soon as they are identified or communicated to me, and will await approval by PEAG before proceeding.
4. I will submit in writing any amendment to the principal applicant and/or co-applicants to the MHRA for approval by PEAG.
5. I understand data will only be provided if Yellow Card data is considered feasible for the research being conducted.
6. I will submit any draft articles to the MHRA for approval at least four calendar weeks before submission.
7. I will ensure that any Yellow Card data is maintained securely and confidentially at all times.
8. I will inform the MHRA of any new drug safety issues identified at the time of recognition.
9. I understand that I will be required to sign a contract detailing the terms under which the Yellow Card data is provided (including the conditions of release listed in section 2.2 of the Guidance Notes on Applications for Access to Yellow Card Data) before any data will be released by the MHRA.
10. To the best of my knowledge the information provided in this application is accurate and comprehensive.

Signature of principal applicant: _____ Date: _____

Signature of co-applicant: _____ Date: _____

Signature of co-applicant: _____ Date: _____

Signature of co-applicant: _____ Date: _____

Please also complete the following protocol check list on the next page to ensure all the necessary information has been included as part of your application. Then add your protocol below the checklist starting on the following page.

PROTOCOL CONTENT CHECKLIST

In order to help ensure that protocols submitted for review contain adequate information for protocol evaluation, PEAG have produced instructions on the content of protocols for research using Yellow Card data. Applicants must complete the checklist below to confirm that the protocol being submitted includes all the areas required by PEAG, or to provide justification where a required area is not considered to be relevant for a specific protocol. Protocols will not be circulated to PEAG for review until the checklist has been completed by the applicant.

	Included in protocol?		
Required area	**Yes**	**No**	**If no, reason for omission**
Lay Summary	☐	☐	
Objectives, specific aims and rationale	☐	☐	
Study Type (Descriptive, Hypothesis Generating Hypothesis Testing,)	☐	☐	
Study Design	☐	☐	
Statistical Analysis Plan (including how you will address missing data)	☐	☐	
Selection of any comparison group(s) or controls	☐	☐	
Plans for contacting Yellow Card reporters (include information sheets, invitation letters, consent forms, copy of ethics committee approval letter, etc)	☐	☐	
Patient group involvement	☐	☐	
Potential limitations of the study	☐	☐	
Plans for disseminating and communicating study results	☐	☐	
Relevant research history	☐	☐	

Voluntary registration of PEAG approved studies

Epidemiological studies are increasingly being included in registries of research around the world, including those primarily set up for clinical trials. To increase awareness amongst researchers of ongoing research, PEAG encourages voluntary registration of epidemiological research conducted using MHRA databases. This will not replace information on PEAG approved protocols that may be published in its summary minutes or annual report. It is for the applicant to determine the most appropriate registry for their study. Please inform the Yellow Card Data Application secretariat that you have registered a protocol and provide the location.

Please add your protocol here, include references where relevant (aim for no more than 5 pages)

Once your application is complete please email this along with any other relevant documents to the following mailbox
type2yellowcarddata@mhra.gov.uk