The STEP database - FREQUENTLY ASKED QUESTIONS

About the Database

Q. What is the STEP Database.

A. The STEP stands for **S**afety and **T**oxicity of **E**xcipients for **P**aediatrics. The Safety and **T**oxicity of **E**xcipients for **P**aediatrics (STEP) Database is a user-designed resource that compiles the safety and toxicity data of excipients that is scattered over various sources and presents it in one freely accessible source.

It holds (1) General Information, (2) Clinical Data, (3) Non-Clinical Data, (4) In Vitro Data, (5) Regulatory References and (6) Reviews in relation to the safety and toxicity of excipients.

Q. What is the purpose of the STEP Database

A. The STEP database is developed for storage and exchange of safety and toxicological data for application in paediatric drug development. It is a unique database that combines clinical and non-clinical data of excipients and allows for easy searching and filtering of the data as per needs.

The aim and purpose of the STEP database is

1. To serve as a freely/publicly accessible evidence base for safety and toxicity of excipients for the pharmaceutical industry, academics, pharmacists clinicians and regulators to make informed decisions.
2. To enhance the prospects for identifying potential safety issues at the initial stages of the development process, when excipients are being screened and selected.
3. To help highlight any relationship between exposure and evidence of clinically significant toxicity in the paediatric age group as a whole, or in paediatric subpopulations.
4. To identify possible differences in expression, types or patterns of toxicity in children compared to adults.
5. To provide a basis for assessing the need for generating new data for paediatric medicines (e.g., bridging studies, juvenile toxicity studies, etc.), in order to clarify what kind of new data, gaps in knowledge or studies may be required.
6. To support companies with their regulatory filings with readily available information.
7. To support and enhance research activities by providing a platform to share the unpublished data and data available with corporate entities.

Q. What is beyond the scope of the STEP database?

A. It is important to understand what is beyond the scope of the STEP database. The most common misapprehensions are (1) that the STEP database will provide critical summaries for excipients safety and toxicity (2) It will provide the list of safe and unsafe excipients (3) It will serve as data analysis/computational tool (4) It will provide thresholds for excipients in paediatrics.

The STEP database is not however meant to serve any of the aforementioned purposes. It is not meant to serve directly as a data analysis/computational tool; it does not include any software that would allow statistical calculations. The STEP database does not critically review or evaluate studies for scientific quality. The STEP database does not evaluate study design strengths,

weaknesses and limitations, whether the evidence it reports supports conclusions in a study, or whether there is conflicting evidence from other studies. The STEP database does not derive quantitative estimates for risk assessment purposes and does not integrate findings among studies.

It is developed for storage and exchange of safety and toxicological data for application in paediatric drug development. It is a unique database that combines clinical and non-clinical data of excipients and allows for easy searching and filtering of the data as per needs.

Q. Who is behind this database?

A. European Paediatric Formulation Initiative and United States Formulation Initiative have developed the database in collaboration. The STEP database is hosted by University College London and maintained by European Paediatric Formulation Initiative (EuPFI). The aim of the group is to provide easy-to-use information resource for safety and toxicity of excipients to the scientific community worldwide. The development of the STEP database was part of the PhD thesis work of Smita Salunke. The software/application has been developed by GVK informatics and data collection and extraction is performed by Synfo Data Services. The overall methodology for data collection, extraction and quality assurance was developed as part of the thesis.

Q. How is the STEP database funded?

A. There are different sources of funds.

1) EuPFI membership fees. The industrial members that join EuPFI pay the membership fees and these funds are utilized for the STEP database project.

2) Global Research in Paediatrics (GRIP)- The STEP database development is partly funded by GRIP. Together with EuPFI, GRIP aims to foster relationships and partnerships with all stakeholders concerned and dedicated to paediatric formulation enhancement. GRIP realises that evaluation of the constructed STEP database is essential and hence contributes to the quality control and testing of the database and works with EuPFI to engage international experts to provide peer review on selected excipients which are of particular concern for young children and neonates.

3) The beta database was partly funded by Piramal Healthcare.

Q. What are Limitations on Use of the STEP database:

A. Your use of this database (“database”) constitutes your agreement and acceptance of these Terms of Use and Disclaimer of Liability. You may use this database solely for your own personal, non-commercial use and you may not use the information found on this database except as provided in these Terms of Use. The Database is not for commercial exploitation. You may not decompile, disassemble, or create derivative works from this Database.

ACCESS TO THE STEP DATABASE

Q. Is there is any restriction on who can use the database? Is it limited to EuPFI and USPFI members.

A. No, there is not restriction and it is not limited to EuPFI and USPFI members. The database is available publicly.

Q. How do I get the access to the database

A. The link to the database is available on EuPFI website. On home page you will find the STEP database box. Clicking on the box will direct you to the database login page.

Q. Is there any license cost associated with use of the database ?

A. No, there is not cost associated to the use of the STEP database. It is available freely and publicly. You only have to register to get the access to the database.

Q. Why do I need to register to use the database? How is the registration information utilized?

A. Benefits of registration –apart from the access to the database, help and literature search requests.

i. Provide an opportunity for the users to test new data & new features of database and applications prior to full release. Give users an opportunity to provide your requirements on what you need and want in an ideal safety and toxicity database and software application.

Support, Training and Feedback:

a Help and support available.

b Training /Tutorials available.

c Ability to submit database and software requirements and feedback for future enhancements to the STEP database.

Please note that the personal information (such as name, email addresses, contact number, organization and country) that you knowingly choose to disclose, is collected for various purposes. These purposes include registering to get the access to the database, requesting further information from us about the STEP database or simply asking a question. Your information is privileged and confidential and will not be shared or released to any organization or business entity other than those affiliated with or working in conjunction with the STEP database development.

Q. How do I register to access the database?

A. On the database page and click on the word “NEW USER - Register Here” to begin the registration process. Completion of the registration process will require providing your Name, Email address, Country and Organzation. Once registration form is submitted, you will receive an email with your user name and password.

Q. When do I need to register?

A. On first time use you must be registered to use the database.

Q. I am already registered. Do I need to do anything else?

A. No, You are now ready to login and use the database. Just save your login details as you will need it every time you want to use the database.

LOGGING IN TO THE STEP DATABASE

Q. I have forgotten my email address. What should I do?

A. Click on the 'Forgotten your email address?' link on the login page and enter your username where requested. Your login email will be displayed on the same page to you.

Q. What do I need to do if I change my email address?

A. You will need to register again as the first time user and send the mail to stepdatabase@eupfi.org to cancel your previous registration.

Q. Can I change my password

A. No, You cannot change your password and have to use the password assign to you by the STEP database.

Q. Can I have my password sent to a different e-mail account?

A. For security reasons, we can only send passwords to your registered e-mail address.

Q. Can you give me my password over the phone?

A. No. All passwords are encrypted. If you call to request a new one, we will only be able to email it to you as above.

Q. When I try to login I am told that either my Email Address or Password is not correct. What should I do?

A. Passwords are case sensitive so check that you are typing letters in capitals where they appear as such. Also, ensure that you are using your login password that is emailed to you after you register. If you have more than one email address, check that the one you are keying in is definitely correct as per the email sent to you confirming your username and password.

Q. Do I have to manually key my assigned login ID each time I login to the STEP database?

A. An individual user may choose to change their Internet Browser settings to allow their assigned login ID to be saved in the Browser Cookie. By choosing to save their assigned login ID in the Cookie, the "Username" field will automatically be populated with their assigned login ID. For assistance you should contact your Information Technology Department. Each user is responsible for maintaining the confidentiality of their username and password.

USER SUPPORT to the STEP database

Q. How do I report that the system appears to be down?
A. Send an email to stepdatabase@eupfi.org

Q. If I have general questions or technical issues with the database, how do I resolve those?
A. Send an email to stepdatabase@eupfi.org

Q. Where can I ask questions about how to use the STEP database?
A. Please post questions about how to use STEP to the stepdatabase@eupfi.org mail list.

Q. I've found an error in the STEP database record, what should I do?
A. It'll help your next search, and the searches of others. Comments and amendments will be reviewed by other curators as a check, but we need the knowledge and expertise of our users to clean up and validate errors. We perform many automated checks and validations when we load compound data into the STEP database. At the very least, please let us know by adding a comment. At the bottom of the page, please click the **Feedback** button and complete the details. The curator will review the comments and we'll update the record where appropriate.

Q. Do you have a video tutorial on how to use the STEP database?
A. Yes. The STEP database video tutorial can be found here.

Q. I am preparing a manuscript for publication and have referred to the STEP database as one of the information resource. How should I cite the STEP database?
A. We greatly appreciate that the STEP database helped you during your research. You can help us maintaining the database by citing the STEP database in your scientific publications. Please use the following reference:

Salunke S, Brandys B, Giacoia G, Tuleu C. The STEP (Safety and Toxicity of Excipients for Paediatrics) database: part 2 - the pilot version. Int J Pharm. 2013 Nov 30;457(1):310-22. doi: 10.1016/j.ijpharm.2013.09.013. Epub 2013 Sep 23. PubMed PMID: 24070789.

PROVIDED FEATURES OF THE DATABASE

Q. What are the distinguishing features of the STEP database?

A. The STEP database allows searching "FOR" excipients and "BY" excipients. This dual nature of the STEP database, in which toxicity and safety information can be searched in both directions, makes it unique from existing sources.

Q. What do you mean by Search BY excipients and Search For Excipients and how are they different?

A. The search interface offers two search modules: "Search by Excipient" and "Search for Excipients".

The "Search by Excipient" module provides navigation tools for selection of specific excipients and should be used when searching for safety and toxicity information of particular excipients. (eg. To find information on propylene glycol or multiple excipients (Propylene glycol, Benzyl alcohol, benzoic acid etc).

The "Search for Excipients" module provides enhanced tools for complex queries allowing for searching for excipients associated with specific studies, effects or pharmacological functions. The users can find the excipients by their adverse effect, administration age, study type and/or route of administration (e.g. which excipients are administered in infants by intravenous route).

Q. What type of information can be found using the Search By Excipients?

A. The "Search by Excipient" module provides navigation tools for selection of specific excipients and should be used when searching for safety and toxicity information of particular excipients. (eg. To find information on propylene glycol or multiple excipients (Propylene glycol, Benzyl alcohol, benzoic acid etc).

Q. What type of information can be found using the Search For Excipients?

A. The "Search for Excipients" module provides enhanced tools for complex queries allowing for searching for excipients associated with specific studies, effects or pharmacological functions. The users can find the excipients by their adverse effect, administration age, study type and/or route of administration (e.g. which excipients are administered in infants by intravenous route).

Q. Why type of information is available in regulatory references section?

A. The "regulatory references and other links" section of the database provides regulatory information on the excipient such as whether the excipient is subject to any regulation concerning the use and safety of the excipient, or whether the excipient is GRAS listed. It provides links to national information on the regulatory status of the substance, pertinent NRC reports, regulation pertaining to the excipients as published in Federal Register, worldwide food additive status (e.g. JECFA, WHO), assessment reports prepared by regulatory agencies, scientific opinions and advice from regulatory and government agencies (e.g. EFSA, European commission, FDA). It provides the information on accepted uses in foods and licensed pharmaceuticals where known. However the status of excipients varies from one nation to another and appropriate regulatory bodies need to be consulted for guidance. With this database, end-users will have access to a single source of information, making it easier to stay up to date and comply with regulations in an efficient and prompt manner.

Q. What type of information is available in "Review" section?

A. The review articles discussing one or more facets of the toxicology/safety of the excipient are compiled in this section of the database. Most of these articles do not contain the specific information that can be extracted as per the data fields into the database. However, they do provide useful information about the safety or toxicity of the excipient or group of related excipients. Some articles may contain a complete, detailed description of the toxicity of an excipient, others may address only a particular aspect of the toxicity and others may only list the excipient in a general discussion of the toxicity of a class of compounds. The list of such references is made available with the URL link to the source.

Q. How to download results from the Database?

A. Export Button is provided on the top menu bar to allow the users to create a flexible, need based information reports that can be integrated it into different applications. The data fields are provided on the export interface for the users to be able to filter/select the fields as per their needs, generate report and save it in PDF or Excel format for further analysis. For instance, to generate the report only for dose and safety or adverse effects data, the user can select the "dose and safety and adverse effects" check boxes and the report will be created with just this information.

Q. Are the user searches stored and if so, are they routinely deleted?

A. We do not store any searches that the end-users run. Neither do we analyse the nature of any searches that are processed through the database.

DATA COLLECTION

Q. How do you select the information sources to retrieve the information for the STEP database

A. Data from various sources have been imported into the STEP database. To date an extensive literature survey has been carried out to identify free and commercially available data sources, providing high-quality structural and/or toxicological data. More than 250 sources have been identified. All the databases/sources were evaluated and prioritised using rating scales with three main categories: (i) user needs, (ii) scope and quality of information, and (iii) ease of use. The databases were then categorised into primary, secondary and tertiary sources. The approach is to first search the primary sources. If the search fails to provide the - data for the excipient, the secondary sources are searched followed by tertiary sources to identify the more recent health effects literature for an excipient.

Q. Can you give examples of typical sources of existing information used for the STEP database?

A. Examples of the many types and sources of existing information include the following:

- Data from publicly available factual databases, such as AcTor, ECHA, TOXNET
- Data from bibliographical databases such as PubMed, Science Citation Index, Scopus, Biosis Preview, Embase, ScienceDirect, etc
- Data from published reports, protocols, handbooks
- Data from unpublished various documents available from legacy sites
- Data generated and submitted by third parties

Q. How are the searches performed and who performs the search?

A. We established a tested and validated logical tool called LESS" (Logigramme for Efficient and Systematic Search) for the development and management of standardised search strategy for systematic literature review. We worked with experts from NIH and Cochrane for the development of this tool.

We focus our searches on the toxicity, safety and pharmacology of selected compounds.

We identified the key bibliographic databases such as PubMed, Embase, Scopus, Social Science Citation Index, Biosis, and International Pharmaceutical Abstracts, and the factual databases such as Inchem, AcTOR, TOXNET and an individual search strategy is developed for each resource.

The following process is used to perform the searches for the excipients included in the database:

- The searches are performed by specially trained information scientists with vast experience in searching information and development of search strategies.
- Standard Operating Procedures (SOPs) have been developed to guide the information scientist on building resource specific search strategies.
- Standard templates are used to report on search results and to measure accuracy of the search strategy.
- The relevance of abstracts/data is estimated independently by two pharmacists, using the inclusion/exclusion criteria.

Q. What type of data are included in the STEP database and will the data be expanded over time?

A. The database currently holds the clinical, non clinical, invitro data, regulatory information and toxicological reviews of 29 prioritized excipients. To date, the STEP database contains a full set of data regarding the selected 29 excipients, covering the general information link to physical chemical properties, and detailed toxicity and safety information. About 700 references of clinical data, 1200 data records of nonclinical data, 500 records from in vitro experiments, 288 references related to regulatory information and other interesting links and finally 233 toxicological and clinical reviews.

The focus of the ongoing project is to increase the number of excipients in the existing database so that a database large enough to be of practical research use will be available. Furthermore, currently the only source of information is published literature, however it is well acknowledged that the vast amount of information is held within the drug companies. Hence companies are encouraged to step forward towards a collaborative effort to contribute their in-house non-confidential data into the STEP database to avoid the duplication of the efforts and save money and time involved in toxicity testing.

Q. Why is the excipient I am looking for not in the results?

A. Names that match your search term will be displayed on the search results page. If you do not see what you are looking for it may be because:

i. You searched for an excipient name that is considered to be a synonym. Look for the name under the 'Synonyms'.
ii. You have spelt it differently to the way that it is spelt in the resource.
iii. It is there but you can't see it because there are many excipients. Try narrowing your search by typing first three characters of an excipient who are looking for
iv. You have limited your search to other excipients using the drop-down menu. Try to reset and search again.
v. The name does not occur in the excipients name or synonyms section because it has not been included in the database covered to date.

Q. How current is the data in the STEP database

A. Information searches, data collection, data entry processes, and data quality control and review all influence the actual date of data release. The first phase excipients searches were performed and data extracted during 2012-2013. While the second phase excipients information were searched and extracted during 2013- 2014. Both these phases have entered maintenance phase now and will updated in 2015. The revised date for each excipient will be available on the excipients results page.

A complete list of the STEP database excipients currently available in the database can be found on the

Q. Why does not the STEP database provide the summary or provide the recommendation on the threshold for paediatrics.

A. There are four reasons:

1. The scope of the database; the STEP database is developed for storage and exchange of safety and toxicological information for application in paediatric drug development. It does not aim to serve directly as a data analysis/computational tool; it does not include any software that would allow statistical calculations. The STEP database does not critically review or evaluate studies for scientific quality. The STEP database does not evaluate study design strengths, weaknesses and limitations, whether the evidence it reports supports conclusions in a study, or whether there is conflicting evidence from other studies. The STEP database does not derive quantitative estimates for risk assessment purposes and does not integrate findings among studies.
2. Second, the database is provided for all end-users (academic, industrial and regulatory toxicologists, pharmacologists, clinicians, researchers, regulators and others). The need and type of information differ according to the user. It might be difficult to provide one summary that fits needs of all users.
3. Third to prepare the summary or thresholds competently and responsibly, an efficient integration of key experts is required. Also thorough process from identification of experts to evaluation of the methodology, reliability, and relevance is needed. EuPFI does not have capacity or funds to undertake this task.
4. Finally, EuPFI cannot accept any responsibility or liability and does not provide a warranty for any use or interpretation of the information contained in the database.

An important task the STEP database is to channel relevant scientific information to consumers and to authorities. Another mission, directed towards the scientific community, is to increase the awareness among scientists of the need to bring multiple aspects of scientific information into use in benefit risk assessment of excipients.

Q. Are companies providing the data for the STEP database?

A. The first step of the STEP database was to create the model on data collection and development of interface and retrieve the information available on public domain. It is well acknowledged that the vast amount of information is held within the pharmaceutical companies and excipients manufacturers/suppliers. Hence companies are encouraged to step forward towards a collaborative effort to contribute their in-house non-confidential data into the STEP database to avoid the duplication of the efforts and save money and time involved in toxicity testing. The near future plan is to include the company-donated data. We have initiated discussion with few companies representing EuPFI and hope to have the data included in the STEP database. If your company wishes to submit the information please contact us at admin@eupfi.org or stepdatabase@eupfi.org and we will provide you with the data collection form.

DATA EXTRACTION

Q. Can you clarify what it means to "curate" information on excipients?

A. Curation of information on excipients means the process of extraction of information (as per the database fields) from scientific texts, such as research articles, reports, books, and standardised for the entry into the database. The overall process involves searching for the information (publications, government reports, data sheets etc.) in several resources (eg. Databases, government websites, internet etc.) through systematic search strategies, screening abstracts and titles (when needed full text articles) for identifying the relevant articles, extracting the specific toxicity data (eg. Experimental design, protocol details, results and conclusions) from relevant research papers and convert it into a form suitable for loading into a database and display on a website.

Q. Who are the Curators for the STEP database?

A. The data curation activity for the STEP database is outsourced to professional curation services provider Synfo Data Services (SynfoDS). The curators at SynfoDS and utilized for the STEP database project have PhDs or equivalent qualification. Educational specialties include pharmacology, toxicology, molecular and cellular biology, physiology, biochemistry, microbiology, and clinical data management. The STEP database curators bring a vast amount of experience in lab research. They are well versed in research methods for safety and toxicity studies. EuPFI has developed a comprehensive training program, curation manual and Standard operating procedures (SOPs) to ensure that SynfoDS curators follow rigorous standards in identifying data elements, and annotating safety and toxicity information of excipients. The curators adhere to the ontology developed by EuPFI for the STEP database project. New curators are trained by a senior curator and do test curation projects for several months before curating independently. In addition to the curation manual and one-on-one training, there is a weekly curation meeting in which standards, policies, and new data types are discussed in order to maintain existing standards and develop new ones. Standards for new data types are developed through consultations with researchers having expertise in those areas, other groups, and the curation group at SynfoDS. Inter-curator disagreements, which do occur even between highly experienced curators, are discussed in weekly meetings with pertinent examples from the literature and, when necessary, consultation with outside experts. Consensus decisions are added to the curation manual.

Q. Can you provide more details on how data is extracted or standardized in the database?

A. As toxicological data may come from different, heterogeneous sources, a ontology driven approach, unifying the terminology and the resources, is critical for the rational and reliable organization of the data, and its automatic processing. Ontology and controlled vocabulary is very useful in standardizing and organizing safety and toxicological data and improving the interoperability between toxicology resources processing this data.

The STEP database curators add data into the database using a curation template that is designed to make data entry as error free and accurate as possible. The template incorporates various controlled vocabularies to supply the terminology that describes the data in a consistent manner. The vocabularies range from simple lists such as excipient names, age group to more complex structured vocabulary of the organ ontology or study type ontology. Curators and STEP database lead member have developed these ontologies and in some cases they are continuously updated by the STEP database lead member with the input from experts in relevant fields, as new research findings dictate the need for new terms. These same controlled vocabularies are used in query forms that end-users see in the STEP database and allow them to more easily analyze large amounts of data for similarities and differences across the species or age groups. While controlled vocabularies are valuable in helping users group data, they are sometimes not specific enough to describe the subtleness of some results. Therefore curation of these data often includes an option for curators to add free text. While free text allows the freedom in adding the experimental details, it is not as amenable to efficient searching as is the use of controlled vocabulary. Hence a good compromise of using both types of data capture is used.

QUALITY ASSURANCE

Q. What quality control processes and measures are in place?

A. The quality of the data entry into the database is an essential element and needs a thorough quality assurance to ensure there are no errors in the database and that the required levels of precision and recall are achieved or exceeded. According to this, strict quality control procedures were implemented at the collection level, involving proof-reading of all output documents and comprehensive checking of selected curated information against the original sources.

1. Primary

Primary quality assurance is performed when a curator initially enters details collected from the source information. A Curator is an experienced scientist with Mpharm/PhD degree and knowledge of pharmacology and toxicology. At this time the individual curator reviewing the study, examines all data reported, to determine if the criteria required for the study to be included in the database are met and the information is then extracted as per the template. A senior curator secondarily reviewed the extracted information. Additionally, all data extracted undergoes automated validation using the Data Validation & Cleaning Tool before it is even received into the second stage.

2. Secondary

Secondary quality assurance for these data is considered to be the review and comparison of the data extracted, and entered into an excel spreadsheet, with the data presented in the actual reference. The secondary review process is conducted by data reviewers who are more experienced than the data curators. They undertake activities to review the completeness, accuracy and quality of the extracted information. Such efforts include verifying that the information extracted is complete (i.e., not missing data/records intended for extraction), contains no typo errors and displays information consistently. This quality assurance effort is conducted on every record entered into the database. In addition, reviewers assist the database team in quality assurance by noting any entry data that is found to have errors during their day-to-day activities.

3. Tertiary

Tertiary quality assurance is implemented following a completion of secondary review. The methods used in this third review include random visual check of data entries, several methods of sorting by data fields to detect inconsistencies, and further investigation into records that contain these inconsistencies. Once the review of all the available fields is

completed, through sufficient quality checks, the Excel spreadsheet is ported into Oracle. Once the data is available in the test version of the database. It is again checked for inconsistences or errors. After quality control measures are satisfied, the information is made available to public.

The overall system of data curation and quality control is managed manually currently as an interim solution and in future it is planned to automate at least some of the functions.

STEP database builds quality assurance (QA) and quality control (QC) measures into each step of the data-collection process, and database QA team has instituted a rigorous QA procedure that is part of a continual, cyclical process. Throughout this process:

We welcome feedback about data quality from users using the database, and we investigate all issues brought to our attention. We frequently review the database to detect data inconsistencies that need correction or verification. We use the data in our own research, which increases our understanding of the details of the data and helps us uncover problems. We are in regular contact with the users email, providing guidance and answering questions about QA/QC issues.

Q. How do you be deal with the issue of toxicity data quality?

A. We deal with issues of data quality currently only as they pertain to accurate representation of the excipient information in the database. We do not quality review toxicity data in in the research papers or source from where the information is retrieved. Rather than directly assessing the quality of experimental data, the database more focuses on the relevancy of the information for inclusion in the database. We only strive to faithfully reproduce the source safety and toxicity data. However, maintaining direct linkages to the original source and providing literature citations and adequate data description better arm a user to place the toxicity data in an appropriate context and make their own judgement with respect to the issue of data quality of the underlying toxicology/safety study.

Q. How do you Locate Text Errors in the data fields?

A. Overall population of the data in the database involves a large measure of human data entry of text information, either directly (through curators) or indirectly (Source-errors), with the inevitable human errors that non-automated data entry entails. Data field entry counts and defined characters of the data fields, enforces consistency of common information across all files. Manual checks and QA reviews have detected and corrected the vast majority of these errors. More recently, however, we have employed programming scripts to perform automated checks on data fields content, both past and new, requiring the text content to conform to the allowed field entry values and basic ASCII text standards. These automated text field scans have located numerous minor typographical errors and some non-standard ASCII characters from imported text field entries. Once located, these errors or inadvertant characters have been corrected. Instituting limits on data field entries (predefined menu choices), and performing automated text field scans on new data entry records before finalizing their entry into the database will prevent such errors from occurring in the future.

Q. How can I find out more about STEP database data quality, excipients, data gathering and extraction requirements, etc.?

A. The best way to find out more about Database is to visit step database webpage, including the Frequently Asked Questions. You can also contact the STEP database support team directly.

MAINTENANCE

Q. How will updates to data within the STEP database be handled?

A. As per the current plan, the data will be update quarterly. Every quarter you will find information for the new excipients in the database. Also for the existing excipients, new data will be provided and existing data will be uploaded. The detailed maintenance scheme is devised to update the existing information. The revised date for each excipient will be available on the excipients results page. In future the aim would be to make the data available as it is curated and reviewed on daily basis.

A complete list of the STEP database excipients currently available in the database can be found on the

Q. How do you plan to maintain and expand this public effort?

A. We cannot expand this public effort without your help, and for this we will need to involve toxicity database sources and the STEP database users more directly in the STEP database collaboration. We hope to entice more users into using the database, and want to encourage their view/feedback on the database. You can help us maintain and this effort database by citing the STEP database in your scientific publications.

Also we have introduced the "SPONSOR AN EXCIPIENT" scheme. This scheme allows the end-users to include the excipients of their choice in the STEP database. If you are interested in any excipient and if it is not included in the database we can search & curate the information for you on priority basis if you 'sponsor the excipient'. Funding and sponsorship can help to deliver the information of safety and toxicity excipients to facilitate paediatric drug development, by financing excipients that could not otherwise have been undertaken under the STEP database project.

Q. How can I help your effort and show my support?

A. The simplest and important thing you can do is to consider using, or encourage others to use the STEP database and provide the feedback on usability of the database. You can also help by citing the STEP database in your scientific publications. The more feedback and citations we get, the more the STEP database gains the acceptance and the more safety and toxicity data of excipients will become available. You can also share your data to be included in the database. Other ways to help are to consider volunteering to be the STEP database reviewer, to report any errors in data or documentation or bugs in the interface. Please do not hesitate to contact us at stepdatabase@eupfi.org

Q. What is "Sponsor an Excipient" Scheme

A. The "SPONSOR AN EXCIPIENT" scheme allows the end-users to include the excipients of their choice in the STEP database. If you are interested in any excipient and if it is not included in the database we can search & curate the information for you on priority basis if you 'sponsor the excipient'. Funding and sponsorship can help to deliver the information of safety and toxicity excipients to facilitate paediatric drug development, by financing excipients that could not otherwise have been undertaken under the STEP database project.

Q. What are the future plans for the STEP database

A. Based on prioritisation, the future plans are

1. To expand the database with more excipients
2. To include the company-donated data and retrieve the information from fee based sources.
3. To expand the database with more data elements (eg. API, patient characteristics, study design etc)

Feedback received through focus groups and other evaluation methods has identified features to be considered for future versions of STEP database.

Your needs are our priorities. Please contact EuPFI with your comments and feedback.

TROUBLESHOOTING

Q: Search performance is very slow - what can I do?

A. Search performance may be impacted by any number of factors - the load on the web site computers or network, the intervening network between the web site and your site, your own network installation, and other factors. We would appreciate that you submit any feedback on search performance by means of an email problem report, as described in a previous FAQ item. Please provide as much information as available, the date/time the search was made, the type of search (e.g., excipient name), and the length of time spent waiting for the search to return (e.g., 10 seconds, 60 seconds, etc.) and whether the search actually ever returned. At a minimum, we will respond with our best assessment of the performance issue.

Q: I can't get the database to display all (or selected) screens and information in a consistent manner - what can I do?

A. We have tested the STEP database on a number of computer platforms and with a number of browsers but yours may not be on the list. Check the information on login page to find which platforms and browsers are supported.

In any event, please submit an email problem report as described in a previous FAQ item. We will attempt to test new platforms and browsers as the need in the science community becomes apparent.

Q. What are the known issues in the STEP database?

A. The known issues in the STEP database are available at **http://eupfi.org/STEP%20Database/KNOWN%20ISSUES%20IN%20THE%20STEP%20DATABASE.pdf**

Q. I have a question that was not answered in the FAQs, or would like to suggest a new feature.

A. Please do not hesitate to contact us at stepdatabase@eupfi.org. We are very happy about feedback!