Populating Data from EFPIA Members, University Participants & Literature for Physiology Database (Task 4.5)

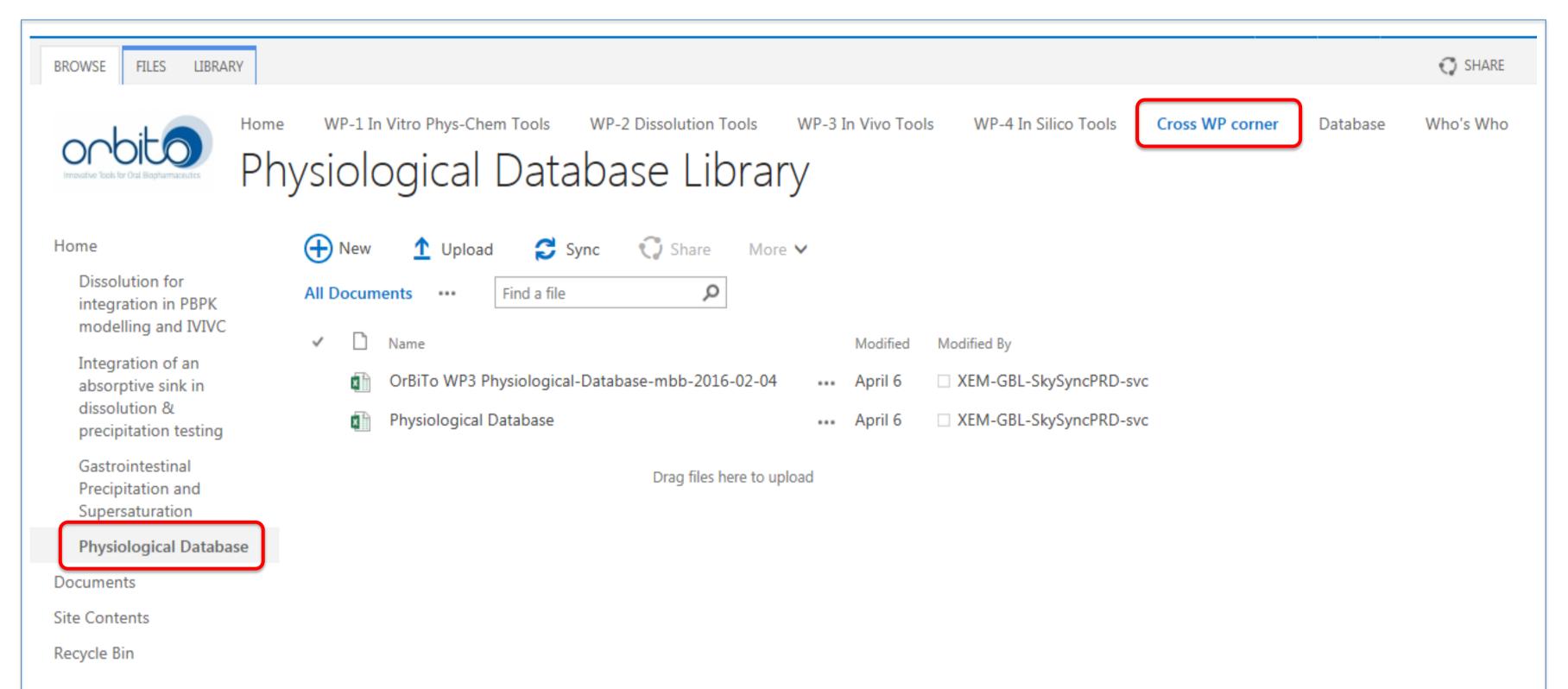[1] Simcyp Limited, UK   [2] Johannes Gutenberg Universitaet Mainz   [3] Sanofi-Aventis Research and Development

❖ **AIM OF THE TASK**
- The main aim of task T 4.5 is to generate a central physiological database and populate it with the support of EFPIA, University partners and literature as a valuable database for future reference.

❖ **BACKGROUND**
- Several physiological values for the GI tract would be generated and/or reviewed in animals and humans during OrBiTO project period. However, these data may be quite scattered into different workpackages and not centrally accessible to all the interested partners.
- A physiological database can be created on the basis of WP3 review and the new data generated under WP1 & WP3 could be used to enrich this database.

❖ **THE DATABASE LOCATION ON THE ORBITO SHAREPOINT**

https://azcollaboration.sharepoint.com/sites/

- Since populating database is a collaborative work that involves the interested EFPIA and university partners across all work packages (WP1 to WP4), the database has been uploaded on the Cross-WP webpage area for easy access.
- Due to budget constraints, we couldn't have a similar database structure as we have created for compounds. However, we can still use an easy to access and flexible Excel template to enter the data.
- Hence, an excel based database structure for uploading physiological database has been created and uploaded on sharepoint for users across all the workpackages.
- For consistency and to avoid any discrepancy across different versions, it is suggested that users sending their data in the Excel template indicated below, to the task leaders.

❖ **DATABASE STRUCTURE**

❑ **DISPERSION STATISTICS REPORTING**
- Stats on measured values, *i.e.* Mean, Median, Mode need to be reported. To have uniformity across entered data, it would be useful if the user reports the dispersion statistics in terms of %CV along with the mean value.
- However, in case of literature review, if dataset is available with "standard deviation" (± STDEV), "Range" or "Percentile", it can be reported. Wherever applicable, please report dispersion statistics along with the measured value in the same cell, e.g.- 2.5 (0.5) and indicate the dispersion particulars (±STDEV, %CV, Range, Percentile) in the table heading.

❑ **INDIVIDUAL MEASUREMENTS AND ETHICAL APPROVAL**
- We strongly encourage users to populate the database with "Individual" data, wherever possible. Users can enter individual datasets along with the related statistics and parameters as mentioned above.
- Referring "Ethical Approval" document of the study (either by linking the document on OrBiTo Sharepoint or by entering reference number of the document, if not available on sharepoint etc.) would be helpful. To conceal traceability of the individual volunteers in the study, it is suggested to use Random number generator (RANDBETWEEN) function within Excel.

❑ **REPORTING UNITS AND REFERENCES**
- The Units used must be indicated in the same row or column where particulars of the measured value are indicated.

Particular	HIF[a]	HCF[b]	Reference (if any)
Bile Salts **(mM)**	X.X (%CV)	X.X (%CV)	3
Buffer Capacity **(mM/pH)**	X.X (%CV)	X.X (%CV)	4

   a. HIF- Human Intestinal Fluid (n=3)
   b. HCF- Human Colonic Fluid (n=2)

- If the dataset entered is a result of literature review, then an additional column indicating the "Literature Reference Number" should be created. The references can be added in sequence at the bottom of the table in the following format.
  1. XXXX et al. (2015) Pharm Res. 10 (14) 123-125.
- Other than the Minimum Essential Parameters, viz- nits of the measured value, Sample size, Dispersion Statistics, Species Used, Analytical method followed, if any, and/or Appropriate References, if the user thinks that any additional information may be helpful in reading/interpreting the measured values from the table, it can be added at the bottom of the table.

❑ **WHAT TO DO IF YOU NEED HELP?**
- If you have any specific query regarding particular dataset your institution is handling, please e-mail to the team Shriram Pathak (**shriram.pathak@certara.com**) and Peter Langguth (**langguth@uni-mainz.de**).

Task/tasks-

Task 4.5. Populating Data from EFPIA Members, University Participants & Literature for Physiology Database

Identified problems/challenges;

- Active participation from all the interested partners across WP's required.

Dependencies and collaboration

- Academic partner Mainz University
- EFPIA partner Sanofi- Aventis R&D

I can continue build on this task;

CONTRIBUTION FROM ALL THE INTERESTED EFPIA AND UNIVERSITY PARTNERS ACROSS ALL WORKPACKAGES REQUIRED IN POPULATING DATABASE

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