

## **FDA: Updated requirements and recommendations for the use of WHODrug**

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During October 2017, the U.S. FDA made some major updates to the recommendations for the use of WHODrug in clinical trials. In the [Federal Register](#), the U.S. FDA announced a requirement for the use of WHODrug Global and the B3-format when submitting study data for studies starting after March 2019. At the same time, the [Data Standards Catalogue](#) was updated to set out the expectation that one of the two latest versions (annual releases) of WHODrug Global should be used. Finally, the [Technical Conformance](#) guide was updated with more clear recommendations for how to use and submit the ATC codes within WHODrug. The UMC welcomes the clarification and considers this to be very helpful for WHODrug users!

## **WHODrug Global Update**

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WHODrug Global is the new, comprehensive and standardised dictionary that is currently being rolled out by UMC. With the recent guidance from FDA for the use of WHODrug Global, UMC has decided to give all June subscribers the opportunity to obtain access to WHODrug Global in March 2018 to secure compliance for studies starting in March 2018. If you are interested in start using WHODrug Global from March 2018, please contact our [Customer Engagement Team](#).

## **New Validation Request Service**

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UMC is developing a new web-based tool for verifying the WHODrug licence of a partner, to be launched in the spring of 2018. The release of the tool aims to give instant request responses and will replace submission of requests via e-mail. Other functionalities include submitting multiple requests in a batch and exporting request results.

## **Extended access to WHODrug Change Analysis Tool (CAT)**

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Previously, some functionalities in WHODrug CAT were reserved for subscribers to two or more WHODrug releases per year. Since all users are moving over to WHODrug Global with the same release interval, full access to the features of WHODrug CAT are now available to all users from December 2017. WHODrug CAT, including the uploading of synonym lists to run impact analyses on a study or company data, may now be accessed from the [UMC website](#).

## **New features in WHODrug Insight**

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UMC is constantly improving the online browsing tool WHODrug Insight. The latest improvements are:

- A new SDG search functionality, allowing users to search for substances and find their respective SDG groupings.
- A new 'look and feel' for the ATC hierarchy, and faster loading times for the ATC and the SDG hierarchies.



Drug search ● SDG ● CDG ● ATC ● CRT Japan ●

WHODrug Enhanced and WHODrug Herbal B3/C3-format March 1, 2017 ▼

Show SDG Tree

Search by SDG substance

Substance ⓘ

omeprazole

Exact match

Search

Substance

SDG

Omeprazole

BCRP inhibitors  
CYP2C19 substrates  
CYP3A substrates  
Drugs for gastric acid related disorders  
Moderate CYP2C19 inhibitors  
P-gp inhibitors  
P-gp substrates  
Weak CYP1A2 inducers

## Save the date for the 2018 WHODrug User Group Meetings

It's time to save the date for the 2018 WHODrug User Group Meetings. Attendance is free of charge for all employees working for an organisation with an ongoing WHODrug subscription.

- **Bangalore, India, February 6, 2018.** UMC, together with the MedDRA MSSO, is pleased to invite you to a joint MedDRA & WHODrug User Group Meeting. In connection with this meeting, UMC will also be offering a full day WHODrug training session on February 5.
- **Basel, Switzerland, April 17, 2018.** Held in connection with the MedDRA User Group Meeting (April 16) and the DIA Europe conference (April 17-19).
- **Boston, MA, USA, June 29, 2018.** Held in connection with the MedDRA User Group Meeting (June 28) and the U.S. DIA conference (June 24-28).

Information on the 2018 User Group Meetings in China and Japan, as well as an additional Industry User Group Meeting in the U.S., will follow. For the most updated information, agendas, and to register, please visit the [UMC Website](#)

## Did you know?

Did you know?

UMC is more than WHODrug! For example, we provide pharmacovigilance training all around the world. Visit the UMC website to read more about [our training events](#).

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