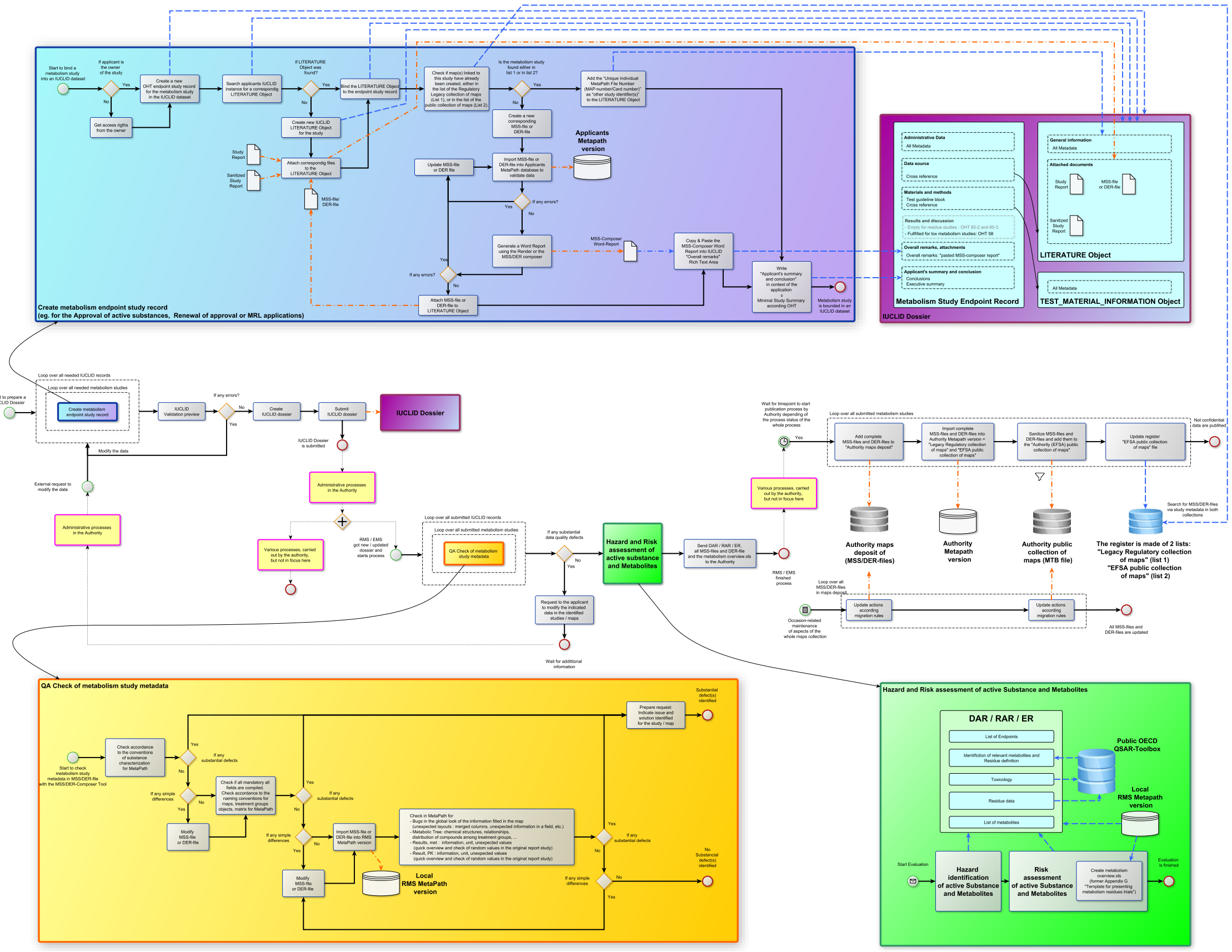
Create metabolism endpoint study record
(eg. for the Approval of active substances, Renewal of approval or MRL applications)
Start to bind a metabolism study into an IUCLID dataset
If applicant is the owner of the study
Yes
No
Create a new OHT endpoint study record for the metabolism study in the IUCLID dataset
Get access rigths from the owner
Search applicants IUCLID instance for a corresponding LITERATURE Object
If LITERATURE Object was found?
Bind the LITERATURE Object to the endpoint study record
Create new IUCLID LITERATURE Object for the study
Study Report
Sanitized Study Report
Attach correspondig files to the LITERATURE Object
MSS-file/ DER-file
Check if map(s) linked to this study have already been created, either in the list of the Regulatory Legacy collection of maps (List 1), or in the list of the public collection of maps (List 2).
Is the metabolism study found either in list 1 or in list 2?
Add the "Unique Individual MetaPath File Number (MAP-number/Card number)" as "other study identifier(s)" to the LITERATURE Object
Create a new corresponding MSS-file or DER-file
Applicants Metapath version
Update MSS-file or DER-file
Import MSS-file or DER-file into Applicants MetaPath database to validate data
If any errors?
Generate a Word Report using the Render or the MSS/DER composer
MSS-Composer Word-Report
Copy & Paste the MSS-Composer Word Report into IUCLID "Overall remarks" Rich Text Area
Write "Applicant's summary and conclusion" in context of the application + Minimal Study Summary according OHT
Metabolism study is bounded in an IUCLID dataset
Attach MSS-file or DER-file to LITERATURE Object
IUCLID Dossier
Administrative Data
All Metadata
Data source
Cross reference
Materials and methods
Test guideline block
Cross reference
Results and discussion
- Empty for residue studies : OHT 85-2 and 85-3
- Fulfilled for tox metabolism studies: OHT 58
Overall remarks, attachments
Overall remarks: "pasted MSS-composer report"
Applicant's summary and conclusion
Conclusions
Executive summary
Metabolism Study Endpoint Record
General information
All Metadata
Attached documents
Study Report
MSS-file or DER-file
Sanitized Study Report
LITERATURE Object
All Metadata
TEST_MATERIAL_INFORMATION Object
Start to prepare a IUCLID Dossier
Loop over all needed IUCLID records
Loop over all needed metabolism studies
Create metabolism endpoint study record
IUCLID Validation preview
If any errors?
Create IUCLID dossier
Submit IUCLID dossier
IUCLID Dossier
IUCLID Dossier is submitted
Modify the data
External request to modify the data
Administrative processes in the Authority
Administrative processes in the Authority
Various processes, carried out by the authority, but not in focus here
RMS / EMS got new / updated dossier and starts process
Loop over all submitted IUCLID records
Loop over all submitted metabolism studies
QA Check of metabolism study metadata
If any substantial data quality defects
Hazard and Risk assessment of active substance and Metabolites
Send DAR / RAR / ER, all MSS-files and DER-file and the metabolism overview.xls to the Authority
Request to the applicant to modify the indicated data in the identified studies / maps
Wait for additional information
Wait for timepoint to start publication process by Authority depending of the process status of the whole process
Various processes, carried out by the authority, but not in focus here
Loop over all submitted metabolism studies
Add complete MSS-files and DER-files to "Authority maps deposit"
Import complete MSS-files and DER-files into Authority Metapath version = "Legacy Regulatory collection of maps" and "EFSA public collection of maps"
Sanitize MSS-files and DER-files and add them to the "Authority (EFSA) public collection of maps"
Update register "EFSA public collection of maps" file
Not confidential data are publihed
Authority maps deposit of (MSS/DER-files)
Authority Metapath version
Authority public collection of maps (MTB file)
Search for MSS/DER-files via study metadata in both collections
The register is made of 2 lists: "Legacy Regulatory collection of maps" (list 1) "EFSA public collection of maps" (list 2)
RMS / EMS finished process
Loop over all MSS/DER-files in maps deposit
Occasion-related maintenance of aspects of the whole maps collection
Update actions according migration rules
Update actions according migration rules
All MSS-files and DER-files are updated
QA Check of metabolism study metadata
Start to check metabolism study metadata in MSS/DER-file with the MSS/DER-Composer Tool
Check accordance to the conventions of substance characterization for MetaPath
If any substantial defects
Prepare request: Indicate issue and solution identified for the study / map
Substantial defect(s) identified
If any simple differences
Modify MSS-file or DER-file
Check if all mandatory all fields are compiled. Check accordance to the naming conventions for maps, treatment groups objects, matrix for MetaPath
Import MSS-file or DER-file into RMS MetaPath version
Check in MetaPath for
- Bugs in the global look of the information filled in the map (unexpected layouts : merged columns, unexpected information in a field, etc.)
- Metabolic Tree: chemical structures, relationships, distribution of compounds among treatment groups, ...
- Results, met : information, unit, unexpected values (quick overview and check of random values in the original report study)
- Result, PK : information, unit, unexpected values (quick overview and check of random values in the original report study)
Local RMS MetaPath version
No Substancial defect(s) identified
Hazard and Risk assessment of active Substance and Metabolites
DAR / RAR / ER
List of Endpoints
Identifiction of relevant metabolites and Residue definition
Toxicology
Residue data
List of metabolites
Public OECD QSAR-Toolbox
Local RMS Metapath version
Start Evaluation
Hazard identification of active Substance and Metabolites
Risk assessment of active Substance and Metabolites
Create metabolism overview.xls (former Appendix G "Template for presenting metabolism residues trials")
Evaluation is finished