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# Additional Features of the P21 Enterprise Version

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# Additional Features of the P21Enterprise Version

There are additional features and benefits on different levels using the P21 Enterprise version:

- On the company level
- Working with metadata and external dictionaries
- For company projects
- Regarding studies
- Handling the issue management

# Additional Features of the P21Enterprise Version... ...for a company

- You can manage user groups with different access rights
- Defining user and group access per Study and Data Package
- Able to create projects to group studies

# Additional Features of the P21Enterprise Version...

## ...working with metadata and external dictionaries

- Being able to load own Metadata and terminologies
- Medical dictionaries could be entered per study

# Additional Features of the P21Enterprise Version... ...for company projects

- Studies having protocol related information for the creation of SDRG and define
- Creation of Data Packages – e.g. SDTM, ADaM, ISS and ISE per study

# Additional Features of the P21Enterprise Version... ...regarding studies (1)

- History of data validation per study – when and who has run the validation
- Able to compare validation versions to see the differences between issues – what is new, what has been solved, how many updates
- Separate overview of “Changes from Last Validation”
- Scores for “Overall progress” per study – and tips how to improve your score
- A Submission Checklist per study – what must be improved and what is missing

# Additional Features of the P21Enterprise Version...

## ...regarding studies (2)

- Issue management with the ability to assign issues to persons and providing comments
- Being able to define status per issue – Open, Fix Now, Fix Later, To Close and Close
- Being able to filter for Status, Assignees, Datasets, Impacts and the possible source of the issue
- Being able to filter for Issues which are not explained (important for generation of the SDRG)
- Entering explanations per issues which will be taken over for the SDRG

# Additional Features of the P21Enterprise Version...

## ...regarding studies (3)

- Supports the creation of the SDRG and define by populating several parts of the draft versions
- Providing issues for define creation



# Additional Features of the P21Enterprise Version... ...handling the issue management

- Providing Explanations for Issues (up to 5 suggestions per issue)
- Mails for assigning issues to user or updates of comments in issues

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