



DH07 Governance for Global Data QC checks

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Melinda, *Tree of Life*

Melinda's artwork reflects her journey living with HIV.

Governance for Global Data QC checks

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Introduction

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QC inventory

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Governance Process

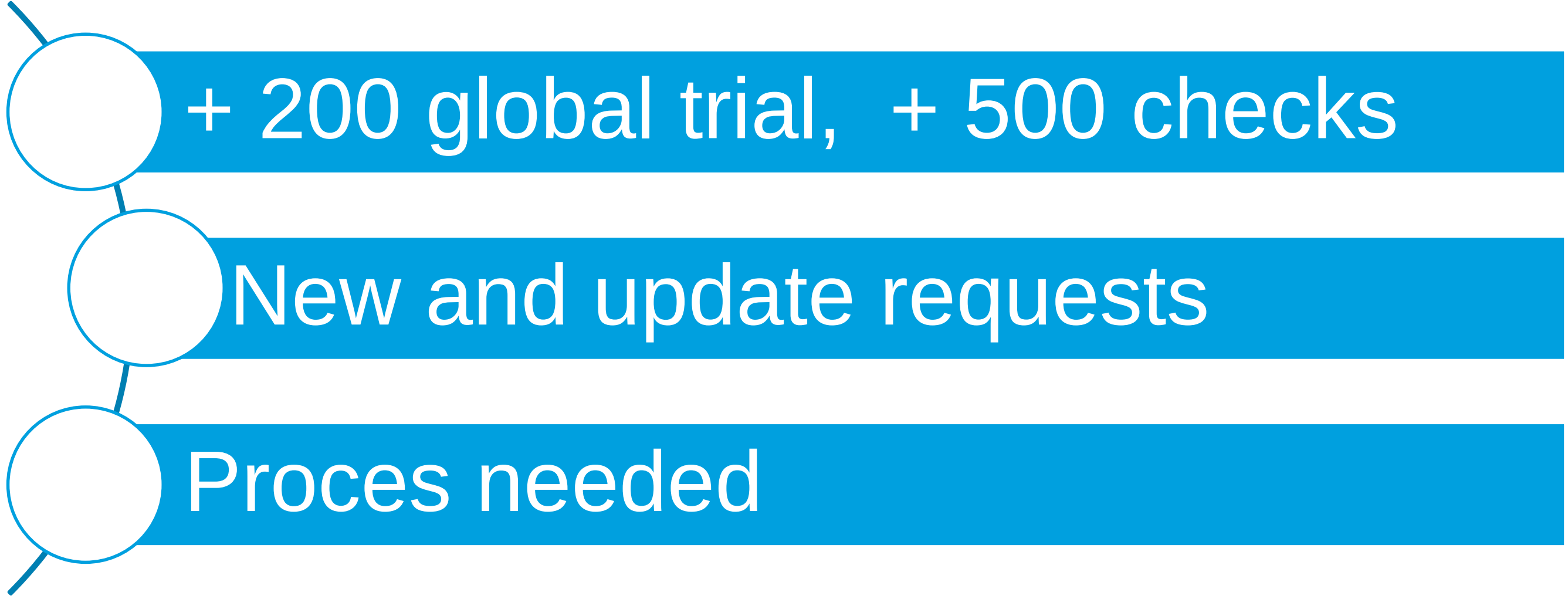
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Conclusion

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Q&A

Introduction



+ 200 global trial, + 500 checks

New and update requests

Proces needed

History

- Request send to different developers
- Request get lost
- Incorrect requests implemented
- Unclear responsibilities

Solution

- Clear governance process
- Clear responsibilities defined
- Everybody knows where to go for a new/update request
- Info that is needed is clear
- Governance team

QC inventory

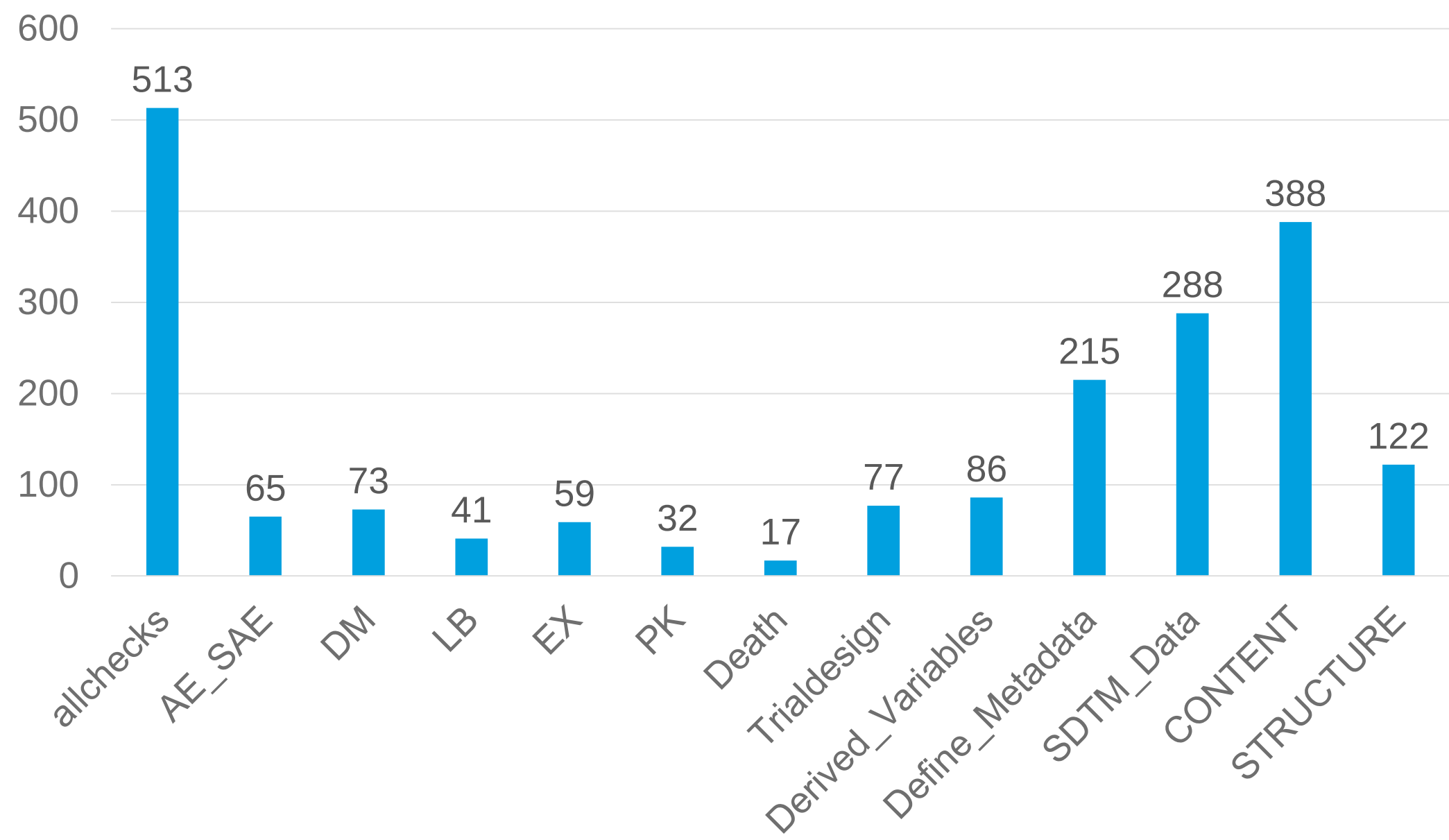
Data model version	Validation status	Validity status	Check ID
JANSSEN_3.2 JANSSEN_SDTMIG_3.1.3_JUL2015 JJ_Pharma_Standards_3.1.3	Fully Validated	Valid	CHECK3130001076

Description	Message	Guidance
If subject has ended trial (record with DSSCAT= TRIAL is present), --DTC (including --STDTC and --ENDTC) must be less than or equal to the latest DSSTDTC.	If subject has ended trial (record with DSSCAT= TRIAL is present), --DTC, --SDTC and --ENDTC must be less than or equal to the latest DSSTDTC.	Note: unscheduled assessments may fall after the latest DSSTDTC.

Severity	Associated domains/groups	Associated variables	GRP_allcheck	GRP_AE_SAE	GRP_DM	GRP_LB	GRP_EX	GRP_PK

GRP_DS_Death	GRP_Trial_design	GRP_Derived_Variables	GRP_Define_Metadata	GRP_SDTM_Data	GRP_CONTEI	GRP_STRUCTURE

QC inventory



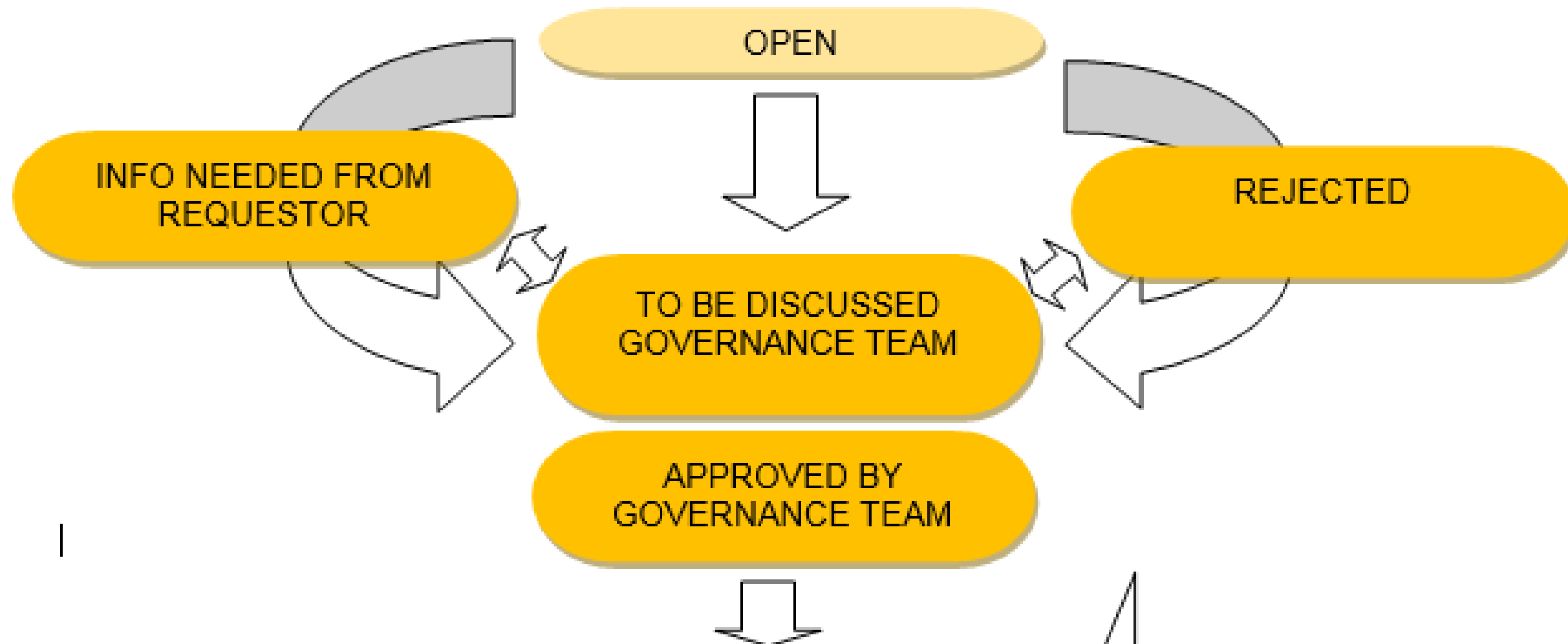
Example of a request

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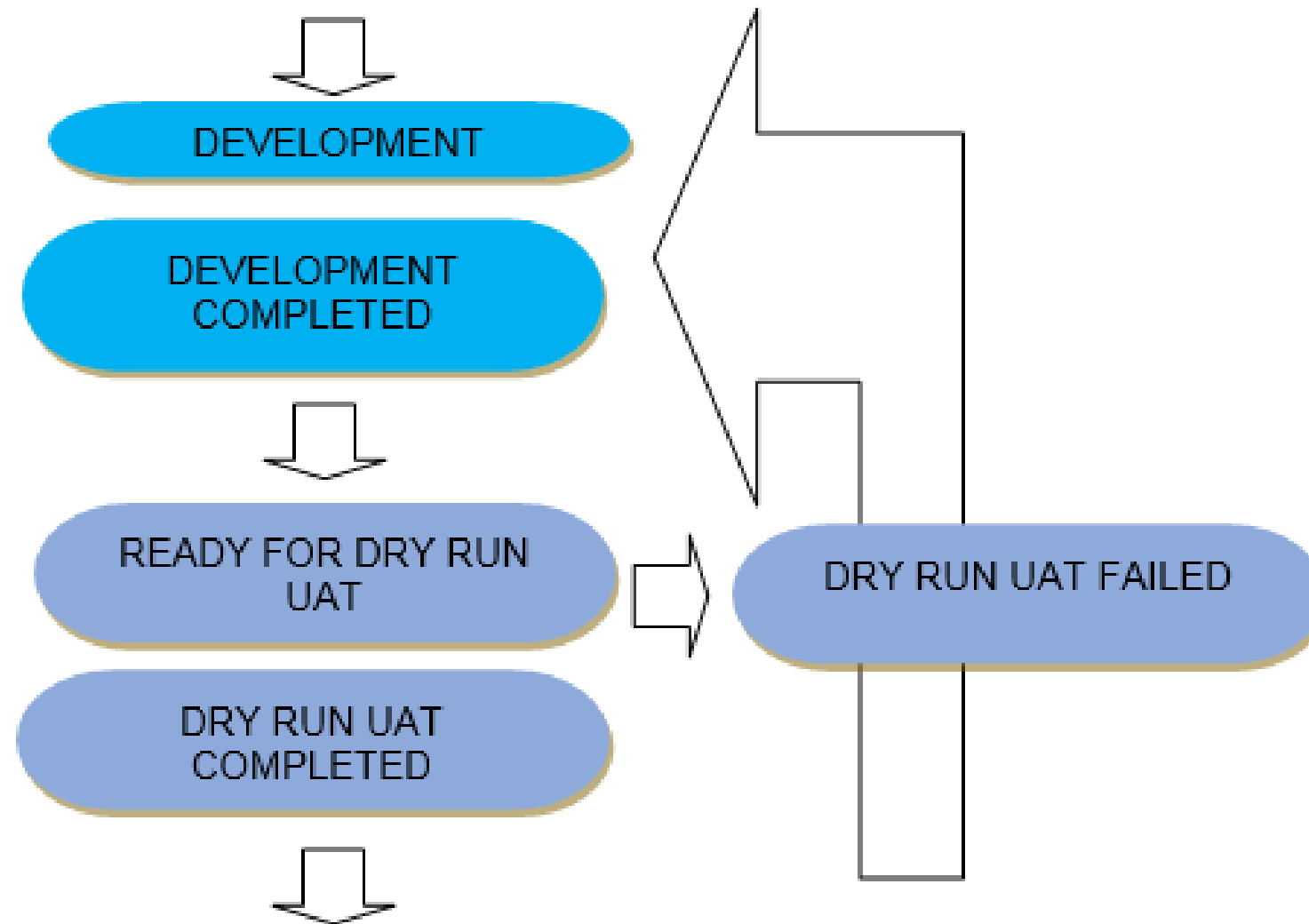
Should be updated to

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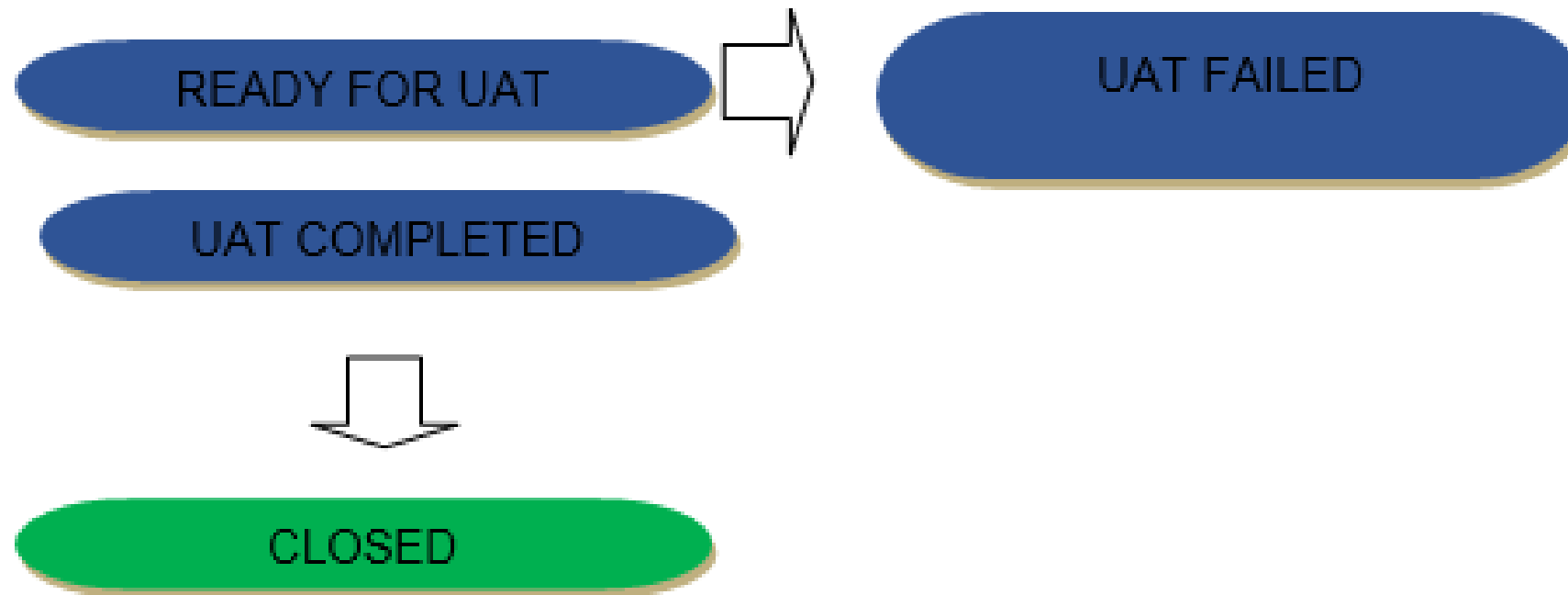
Governance process



Governance process



Governance process



Back to the request

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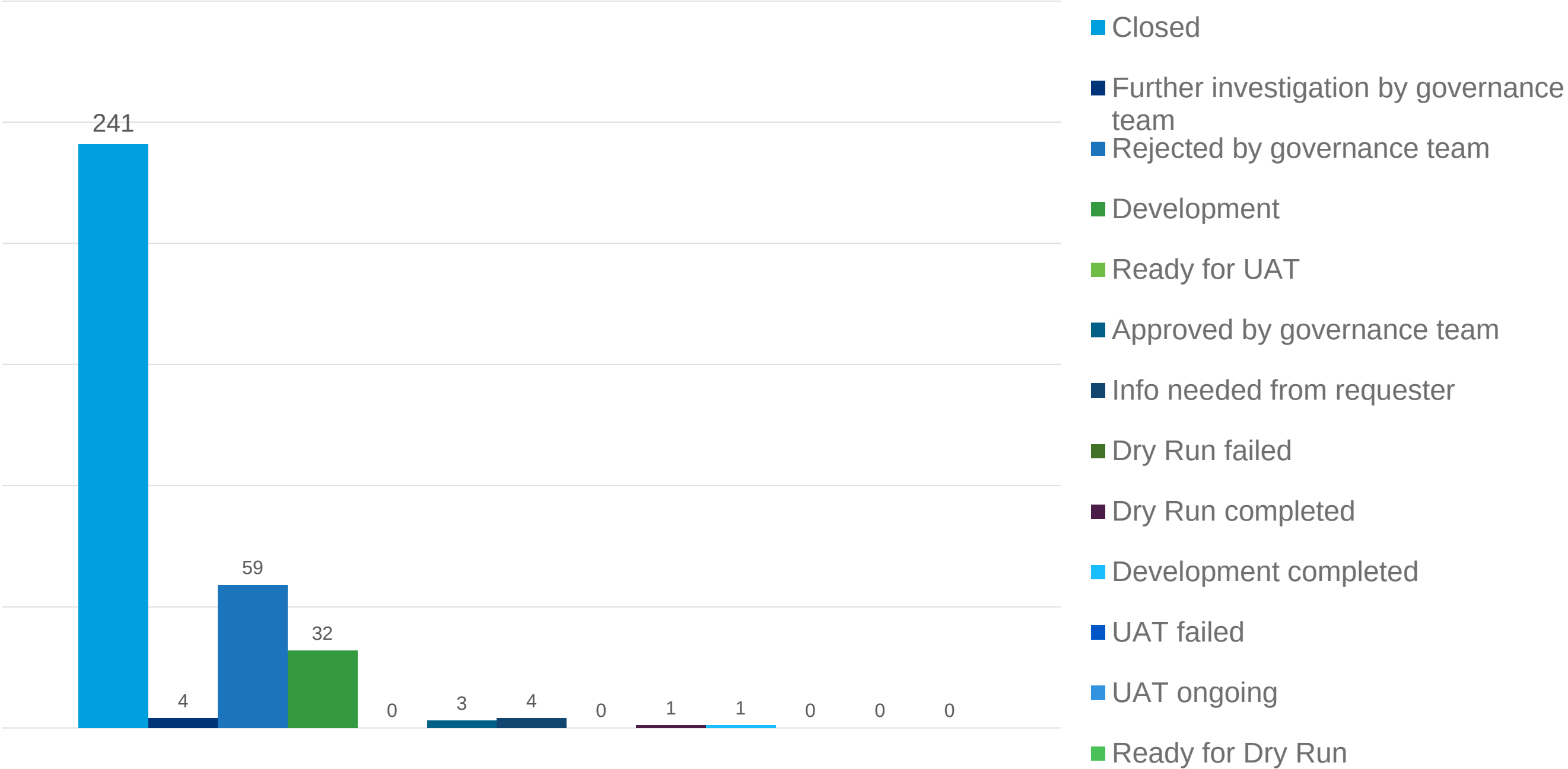
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Conclusion

- Efficient process
- Consistent and complete QC
- Status of request is always available
- Whole department has access

Status





Questions

contact details

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Skin cells at 20x magnification

