
**Paper DH07**

# Governance for Global Data QC Checks

Kristien Nuyts, Janssen Research & Development, Beerse, Belgium

## ABSTRACT

The Janssen Data Management department handles more than 200 trials executed by DM CRO partners. To efficiently perform data QC on all these trials +- 400 general QC checks have been developed and are available to all data managers in a QC inventory with clear description and message. To handle requests for updates to existing checks and requests for new checks we have created a governance process. All requests are gathered in a SharePoint list, and every request is reviewed by a governance team consisting of data managers from different therapeutic areas with data standards knowledge. Once at least three governance team members have agreed with the proposed update the request is approved and sent for development to the programming team. After development and successful 2 step UAT the updated QC check is made available to the whole DM community.

## INTRODUCTION

The Janssen data management department handles more than 200 trials executed by DM CRO partners. To efficiently perform Data QC on all these trials +- 500 general QC checks have been developed and are available to all data managers. The QC inventory provides an overview of these general QC checks with a clear description, message and guidance. In the past there was no clear process to update and create new checks. This resulted in incorrect check updates or big delays in development because responsibilities were not clearly defined. To efficiently handle requests for updates to existing checks and requests for new checks we have created a governance process. In this paper we explain the whole governance process from start to finish.


## QC INVENTORY

The QC inventory provides an overview of all global checks that are available to the data managers. Info that is available is to which data standard (SDTIM IG 3.1.3 or 3.2) the check is applicable, a clear description, message and guidance. Different checks are divided in different groups so that depending on the scope of the QC different subsets of check can be selected. Groups that are available are: all checks, AE_SAE, DM, LB, EX, PK, DS_Death, Trialdesign, Derived variable, Define_Metadata, SDTM_data, Content, Structure.

| 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 |
|---|---|---|---|---|---|---|---|---|
| MEDIUM | GRP_CONTENT,GRP_allchecks | | X | | | | | |

| GRP_DS_Death | GRP_Trialdesign | GRP_Derived_Variables | GRP_Define_Metadata | GRP_SDTM_Data | GRP_CONTE | GRP_STRUCTURE |
|---|---|---|---|---|---|---|
| | | | | | X | |

**Figure 1: QC inventory overview – all properties**

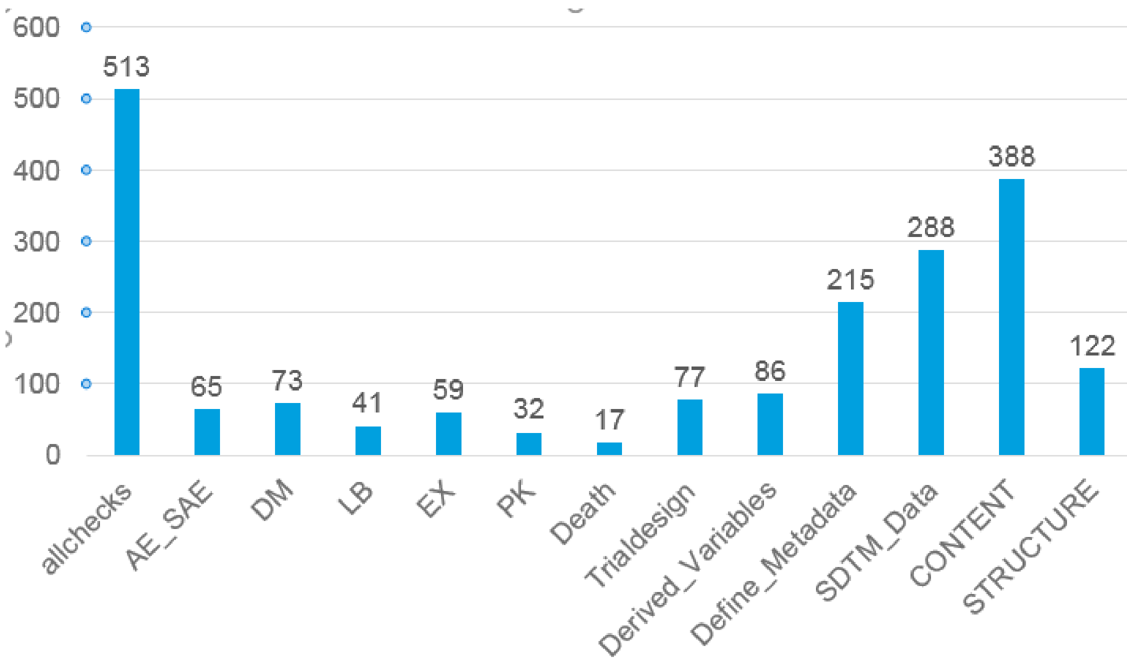



**Figure 2: QC inventory – group overview**


**PROCESS FLOW**

The below flow describes the process for all new check requests or request for update to existing QC check programs.

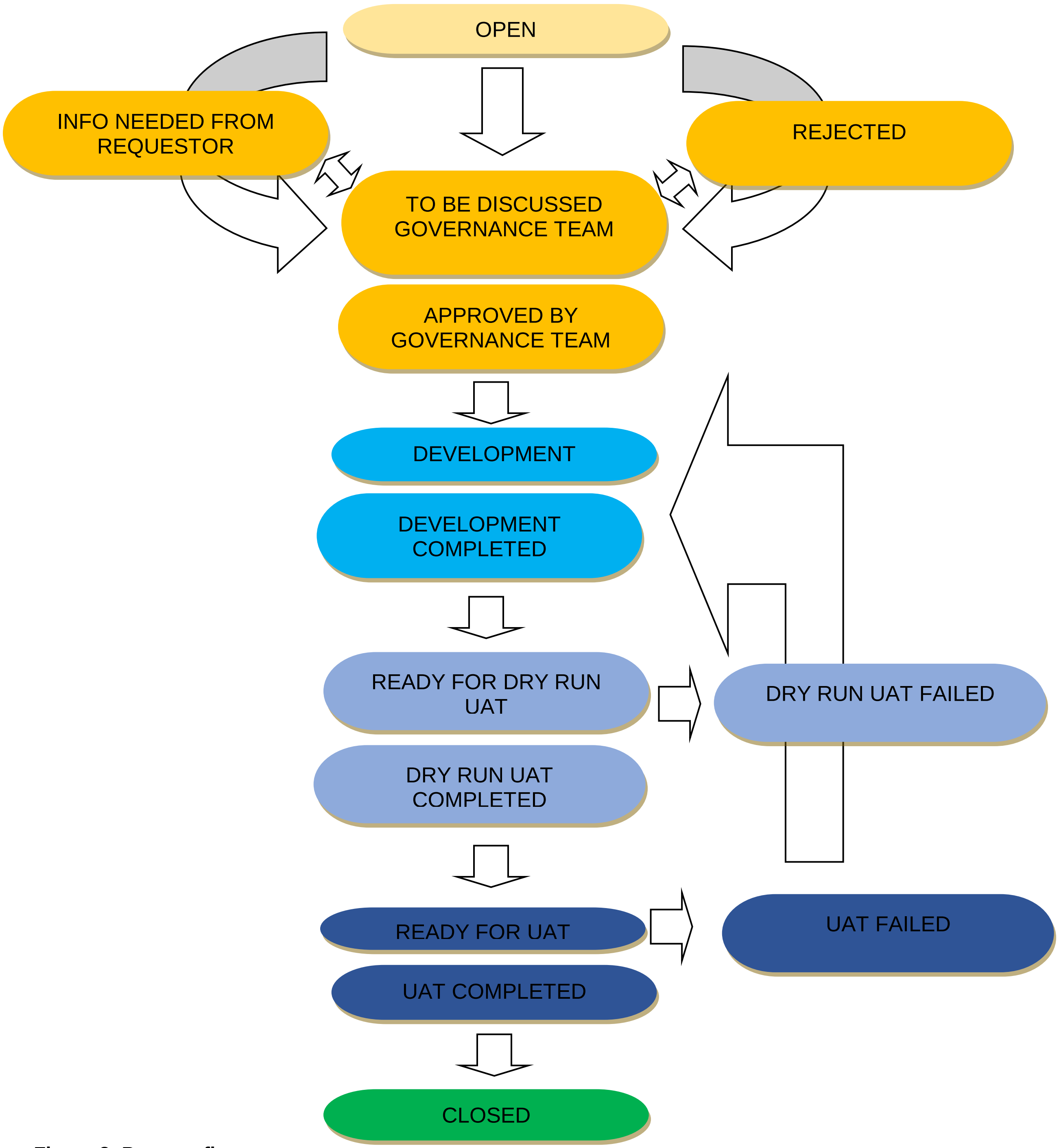



**Figure 3: Process flow**

**REQUEST**

When a data manager identifies the need for a new check, before creating a new check request the data manager should verify in the QC inventory if a similar check/program exists already. If the check does not exist yet a new request can be created in SharePoint with the status Open.
When a data manager identifies the need for an update to an existing check or program, the data manager will first verify if an update request is already present in Sharepoint. If a similar request has already been submitted a new request should not be created. If the request has not already been submitted a new request can be created in SharePoint with the status Open.
The request must include enough documentation and details to enable the governance team to evaluate the request and either approve or decline the request. The documentation must include a link to trial datasets, metadata, define.xml and related exceptions table together with a clear description of what is expected of the check on this data. The requestor should also think about other scenario's that may be present or not in the trial data for which the check needs to provide exceptions or not. All this info is gathered in the "Check Update Request Form" that should be completed and attached to the request in Sharepoint.

The following fields should be completed for the request in SharePoint.
Category: indicates the type of the request, if it is a check or a job. We have different types of programs and checks that are part of one global job that is available for all trials. We also have different jobs that contain one or more separate checks.

**Check Number or Job Name**: For existing checks or jobs the correct number should be provided.

**Request Type**: indicates the request type, new or update guidance / Update GRP variable: This is ticked for updates to the guidance or group assignment.
Update programming: This is ticked if the logic of the check should be updated
New request: This is ticked when a new check or job is requested
Information: Is ticked if more information on the check logic is requested

**Therapeutic area:** Indicates which therapeutic area the reference trial belongs.

**Request status**: indicates the status in the process flow (see process flow overview)

**Bugfix**: This should be checked in case the check should be deactivated while the update is being worked on.
Request details: Clear description of the requested update or new request is provided. Description should be clear for programmers.

**Test data**: Link to the test data is provided.

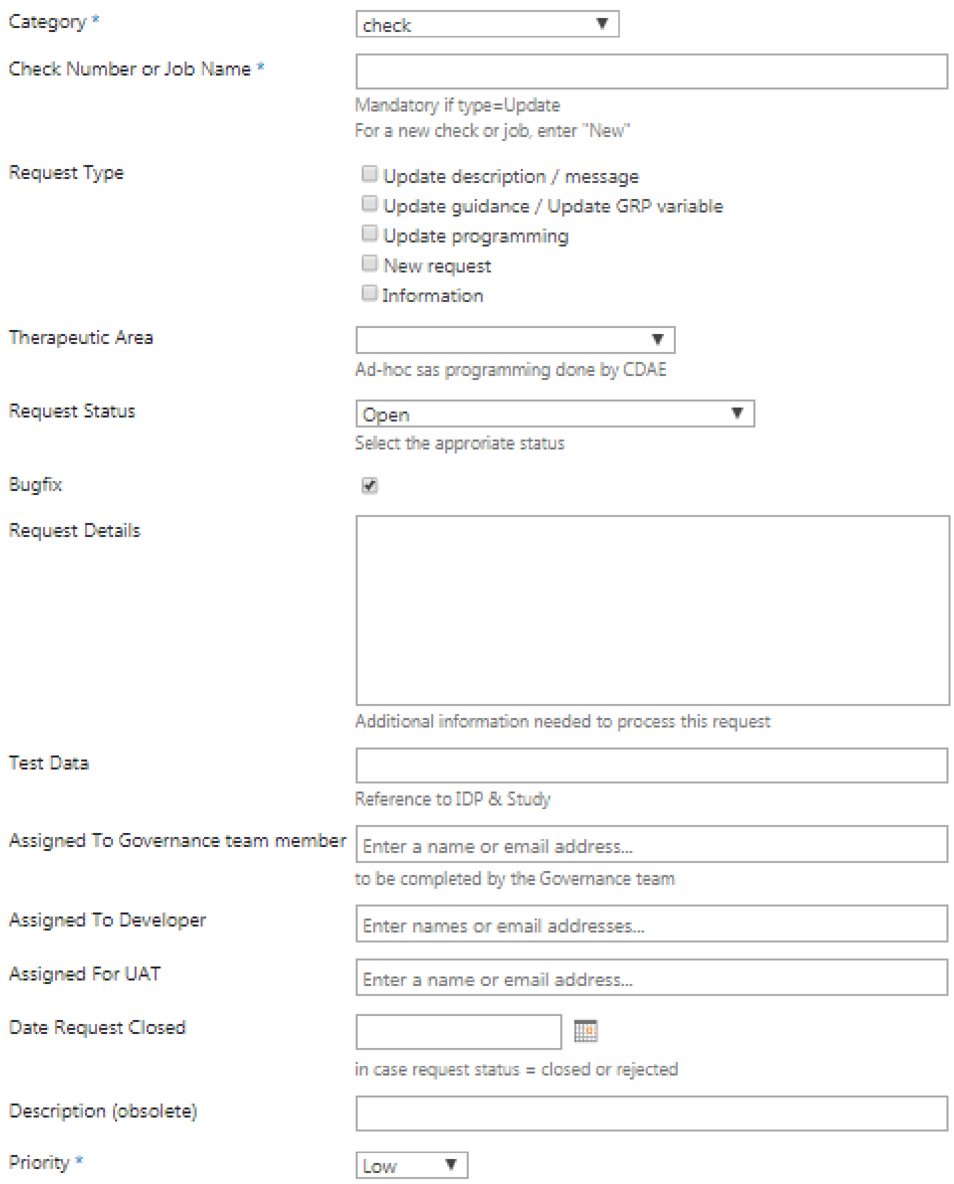
**Assigned To Governance team member**: Governance team member that follows up on the request enters his name here.

**Assigned To Developer:** Developer that programs the update enters his name here.

**Assigned For UAT**: UAT-er that plans the UAT enters his name here.

**Date Request Closed**: Date request is closed is here

**Priority:** Is completed as Low, Medium or High. Low is used for updates that improve the check or check output but is not very urgent for implementation. Medium is used for updates that will greatly help interpretation of the check output. High is used for important updates for example in case current output is not correct.



| | |
|---|---|
| Category * | check |
| Check Number or Job Name * | Mandatory if type=Update<br>For a new check or job, enter "New" |
| Request Type | Update description / message<br>Update guidance / Update GRP variable<br>Update programming<br>New request<br>Information |
| Therapeutic Area | Ad-hoc sas programming done by CDAE |
| Request Status | Open<br>Select the approriate status |
| Bugfix | ☑ |
| Request Details | Additional information needed to process this request |
| Test Data | Reference to IDP & Study |
| Assigned To Governance team member | Enter a name or email address...<br>to be completed by the Governance team |
| Assigned To Developer | Enter names or email addresses... |
| Assigned For UAT | Enter a name or email address... |
| Date Request Closed | in case request status = closed or rejected |
| Description (obsolete) | |
| Priority * | Low |

**Figure 4: Request in Sharepoint**


# Check Update Request Form

**Requestor information**
Name:
e-mail:
Role:
Date of Request:

**Check Information**

| Check ID | Sub Check ID | Output Variables | Check Description | Message | Guidance | Severity | Current groups |
|---|---|---|---|---|---|---|---|
| CHECK313000XXXX | | Ex. STUDYID, DOMAIN, USUBJID, EXSEQ, EXTRT, EXDOSE, EXREFID, EXLOT | Ex. For every record where EXREFID is completed EXLOT should be completed. | Ex. EXLOT missing while EXREFID is not missing | Ex. EXLOT should be completed if EXREFID is completed, derived based on SML at time of DBL. | Ex. LOW, MEDIUM, HIGH or INFORMATIVE | |

**Change Request Information**

| CHECKID | Change Request | New Output Variables | New Description | New Message | New Guidance | New Severity | New Groups (can be completed by governance team) |
|---|---|---|---|---|---|---|---|

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| CHECK313000XXXX | Please provide as much information as possible | Specify Update, New Output Variables or: “No Update needed to output variables. | Specify Update, New Description or: “No Update needed to Description” | Specify Update, New Description or: “No Update needed to Message” | Specify Update, New Description or: “No Update needed to Guidance | Specify Update, New Severity or: “No Update needed to severity | |

Check should work on following data model version

| Data model | Data model of Trial used to check the update (to be completed by requester) | All Data models the check should work on (to be completed by governance team) |
|---|---|---|
| JANSSEN_3.2 | | |
| JANSSEN_SDTMIG_3.1.3_JUL2015 | | |
| JJ_Pharma_Standards_3.1.3 | | |

### Test Data

Please provide a stable path to the test data and metadata, make sure to copy the test data and metadata to a permanent folder so they are also available when the issue is solved in the data.

Domains:
Exception report available: Yes/No
Exception report location:

Test data available: Yes/No
Test (meta)data location:

### Test Scenario

Following test scenarios should be available
(Test scenarios to be completed below)

**Figure 5: Check update request form**

#### REVIEW BY QC CHECK GOVERNANCE TEAM

Upon receipt of a new request, a member of the governance team investigates the request. Starting with entering his name in the Assigned governance team member field. The governance team member verifies if all needed info is present. If the request is not complete, the requestor will be contacted to provide the missing info, and the status will be updated to info needed from requestor. If request is clear and complete the governance team member verifies if request does not overlap with any other outstanding requests. If an overlap exists, the status is updated to rejected with a clear explanation of the reason. If all info is complete, the governance team member prepares the request for discussion in the governance team meeting by updating the status to “to be discussed by governance team”.
The Governance team meets every other week in a team forum. Prior to each meeting comments on check requests are gathered so that team members can prepare for the meeting and the meetings can be held in an efficient way.

If at least 3 governance team members agree with the proposed update and don't have any further comments or questions, the request can be finalized by the assigned governance team member and status is updated to "Approved by Governance team".

**DEVELOPMENT**

The programming team assigns developers to each request. The developer is responsible for translating the scenario's into technical specifications and to make sure that all scenarios are covered in the test data. Extra test data should be created as applicable.
Once the programming is completed, the developer will perform a verification to see if the program runs without errors, with high performance.
Once this is completed the status is updated to "development completed".

**DRY RUN UAT (USER ACCEPTANCE TESTING)**

Once development is completed, the programming team makes the check available for Dry run UAT. In the Dry run UAT process, governance team members run the check on their trials to see if the updated check performs according to the expectations. Governance team members provide their feedback in the team forum. Once approval has been completed successfully by at least 3 team members, the status of the request is updated to Dry Run completed successfully.
As a next step the programming team makes the check available for official UAT in HPALM (our testing/tracking tool).

**OFFICIAL UAT IN HPALM**

UAT testing will occur according to the official UAT process in HPALM. The Programming team creates the official test steps, once this is done, the status is updated to Ready for UAT. Then a UAT-er can enter his name in the Assigned for UAT field indicating he will take on UAT of this check. Once the UAT-er completes the UAT successfully he will update the status to UAT completed.

**CLOSURE OF REQUEST**

After successful UAT, the programming team will make the necessary updates to the documentation and the QC inventory.
If needed a new training for GDM's is foreseen, this is done in collaboration with the governance team. The check is released into production and the status in SharePoint is updated to "Closed".

## CONCLUSION

Improving the completeness and the quality of the QC checks, both for data structure and data content, has a great impact on the business. It brings efficiency in the daily work of the data managers through the organization. It also allows consistency in the way the QC is done cross studies/compounds.

Having a centralized place to collect feed-back/idea's and to identify possible gaps results in a better oversight of the work delivered by our partners.

The implemented governance process for the global Data QC checks works very well and provides a good framework for suggested updates and new check requests. At any time, the status of a check request can be verified, as this information is available to the entire department.

Since the implementation of this process +-200 updates to the checks were handled. Updates made range from updates to the programming of the checks, to only updating of the guidance for easier interpretation.

Currently +- 40 request are in different stages of the process.

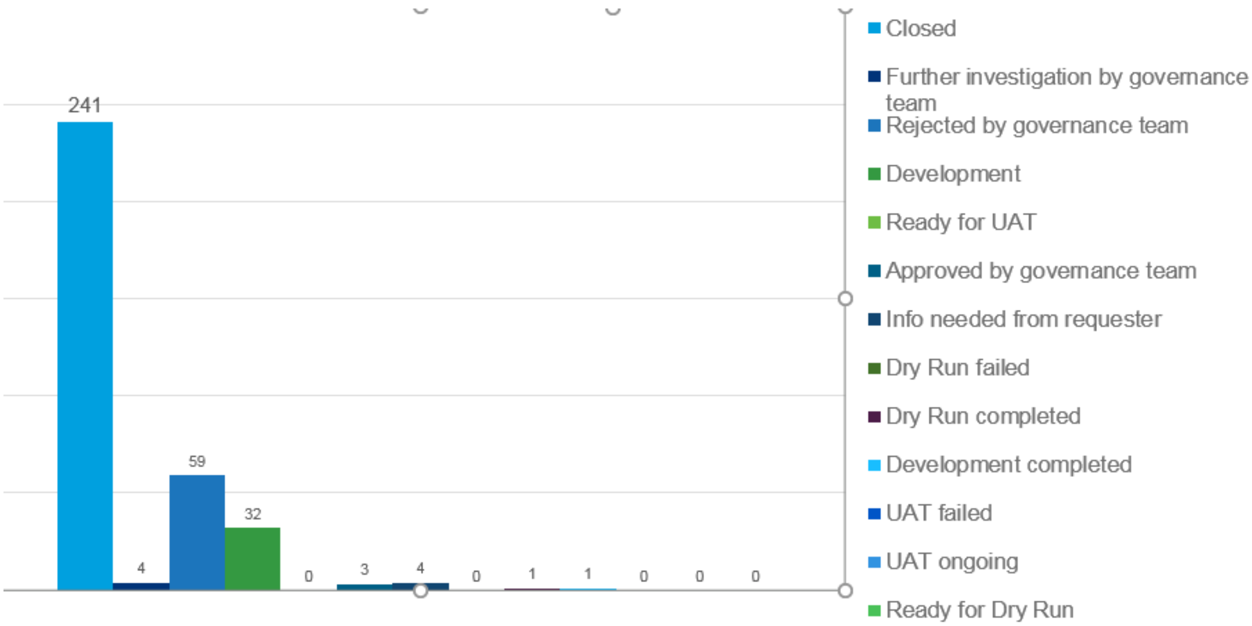




**Figure 6: Status of requests since implementing the process**

## ACKNOWLEDGMENTS

Thanks to all members of the data QC governance team, developers, UAT-ers and requestor for making this an efficient governance process.

## CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Kristien Nuyts
Janssen Research & Development
Turnhoutseweg 30
2340 Turnhout
Work Phone: 0032/14641232
Email: knuyts6@its.jnj.com
Web: www.janssen.com