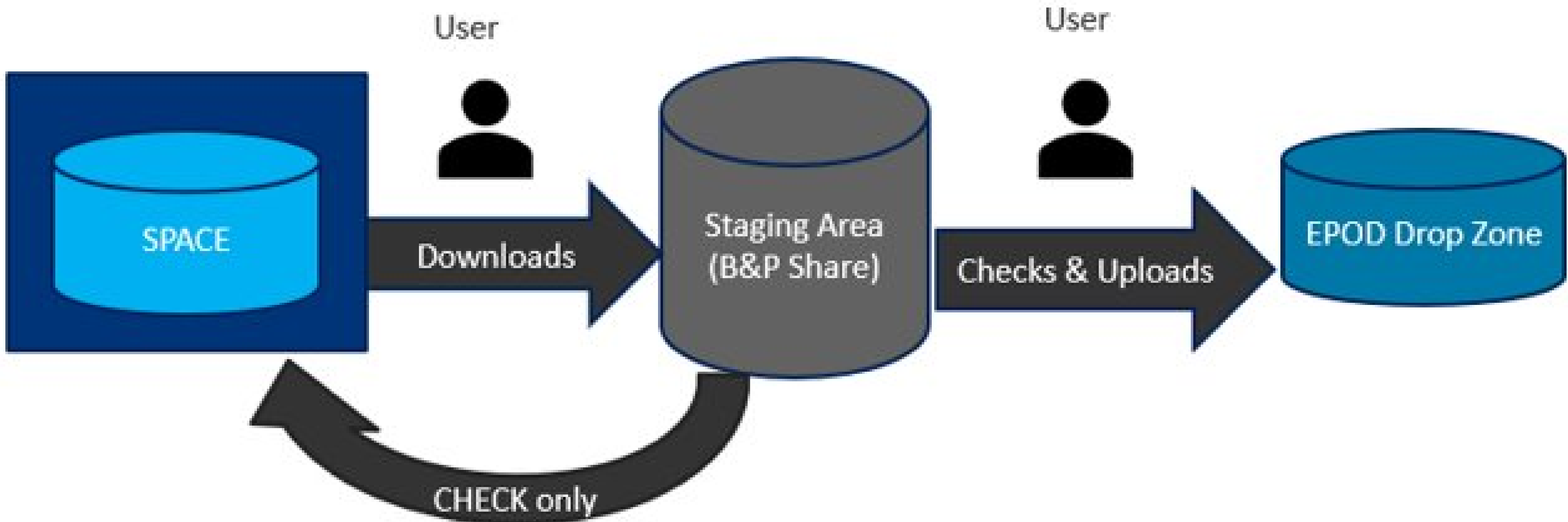


Background Issues with manual submission process:

- QC Checklist inconsistently signed
- Checks were being missed or misinterpreted
- Lack of submission requirements experience
- Incorrect files used in the package over time
- Time consuming manual process involved in sharing the final package with the Janssen Regulatory group
- Wrong files could be copied to the manual eCTD folder structure in the Staging Area
- Extra folders being created by Submission group in final EPOD Drop zone that may not be required
- Human errors in the define.xml and ADRG.pdf creation process

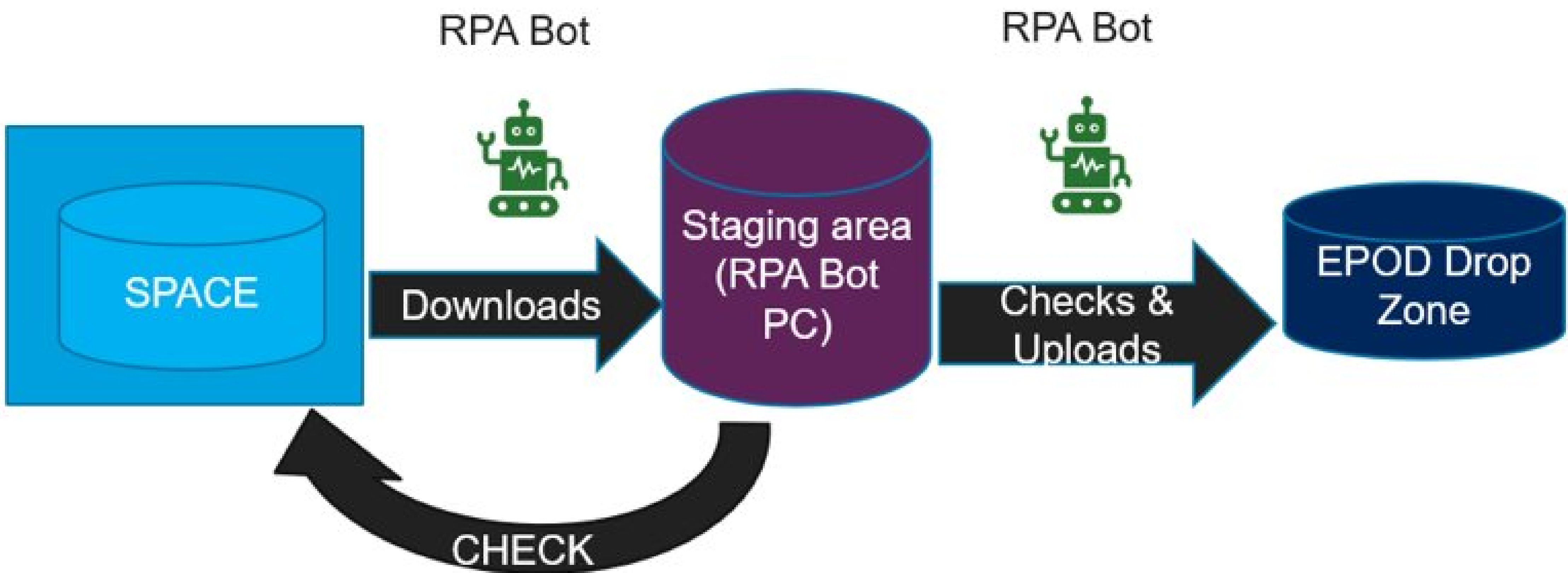
Old Process:



ADaM RPA Bot highlights:

- Only ADaM standard studies supported
- Checks hyperlinks & bookmarks are working
- Checks datasets, programs and misc folders have appropriate files and structure of eCTD
- Eliminates the need for a manual staging area between Programming and Janssen Regulatory group
- Simplifies QC Checklist and checks that a signed version is available at completion
- Verifications of file formatting (checks that all regulatory authority pdf requirements are met)
- Automated delivery to the ePOD Drop Zone with the appropriate eCTD structure in place
- Can be used to check the submission package throughout the lifecycle of the study when first available and not just at the end ('Check' option and 'Check & Deliver' option)
- Has been used on in-house created packages and also vendor created packages so we can then give assistance based on Bot report

Future /Current Process:



We utilise an ADaM Submission Check and Deliver BOT Request form that requires the following input:

- Study Name
- Request Type ('Check' or 'Check & Deliver')
- Datasets Location
- Programs Location
- Misc (listings) Location
- EPOD Location
- Signed QC Checklist (Required for 'Check & Deliver' option)
- Latest P21E Report (Required for 'Check & Deliver' option)
- Requestor e-mail

Once Submitted there is a Request Status in the live form that will indicate that the package is 'In-Progress' and once finished will indicate 'Completed' or 'Failed'. A Failure will result in an automated e-mail to the Requestor with the issues that need resolving until all are resolved and a Success e-mail is received:

This is an automated message from the automated ADaM Submission Checks. Please do not respond to this email.

Check Outcome: **FAIL**

ADaM Package check result: **FAIL: Package has error and cannot be delivered to EPOD.**

No.	Error Message	File Name
1	Error:PDF has one or more invalid property;	datasets\adrg.pdf : Title, OpenBookmarks: 1. Introduction, 2. Protocol Description, 3. Analysis Considerations Related to Multiple Analysis Datasets, 4. Analysis Data Creation and Processing Issues, 5. Analysis Dataset Descriptions, 5.2 Analysis Datasets, 6. Data Conformance Summary, 7. Submission of Programs,
2	Error:XML file contains broken bookmarks and/or hyperlinks:	define.xml: #decodelist,

This is an automated message from the automated ADaM Submission Checks. Please do not respond to this email.

Check Outcome: **Pass**

ADaM Package check result: **SUCCESS: Package has passed all the checks and delivered to EPOD.**