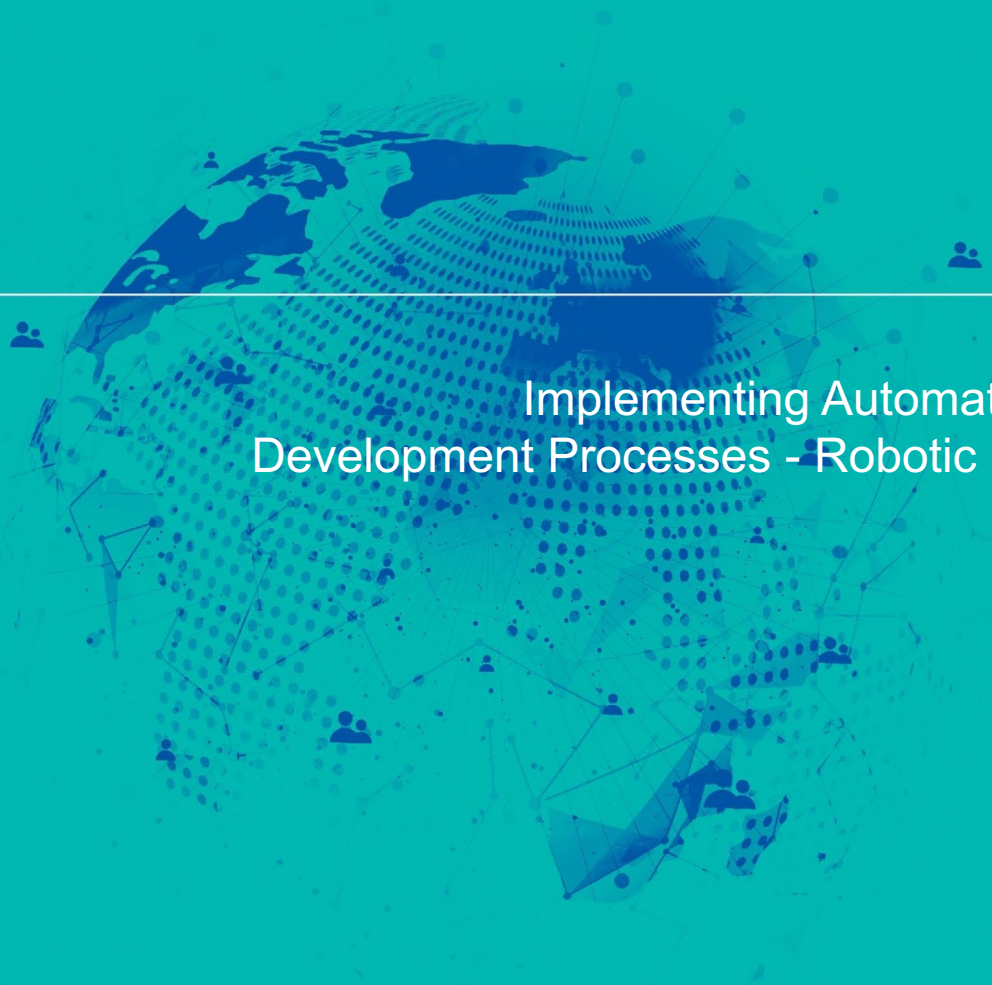

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Single Day Event

Implementing Automation Solutions to Streamline Drug Development Processes - Robotic Process Automation (RPA) BOTs

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Disclaimer

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Background

- Study data included in electronic submissions must be in a **format that a Regulatory Health Authority (RHA) can process, review, and archive**.
- An **RHA may refuse to accept an electronic submission package**, if the study data format is not submission compliant.
- Data intended for a submission to Regulatory Health Authorities must:
  - be **compliant** with the submission requirements
  - undergo a **QC process**
  - be delivered to the Submission Publisher in the **appropriate format/structure**
- **RHA release requirements and Sponsors implement**.

J&J Implementation

- J&J has developed a series of guidance and tools supporting processes related to creating submission-ready documentation to support clinical data submissions.
- It includes a suite of tools that is **using Robotic Process Automation (RPA) BOTs** :
  - **automated checks** on submission packages
  - **automated delivery of the said package** to the internal electronic publishing output network drive in accordance with **Electronic Common Technical Document (eCTD) folder structure** needed for publishing

What are RPA BOTs ?

RPA: Robotic Process Automation

BOT: short for roBOT

Digital Workforce

Interact with any system or application the same way a human worker would

AUTOMATE certains tasks without specific instructions from human

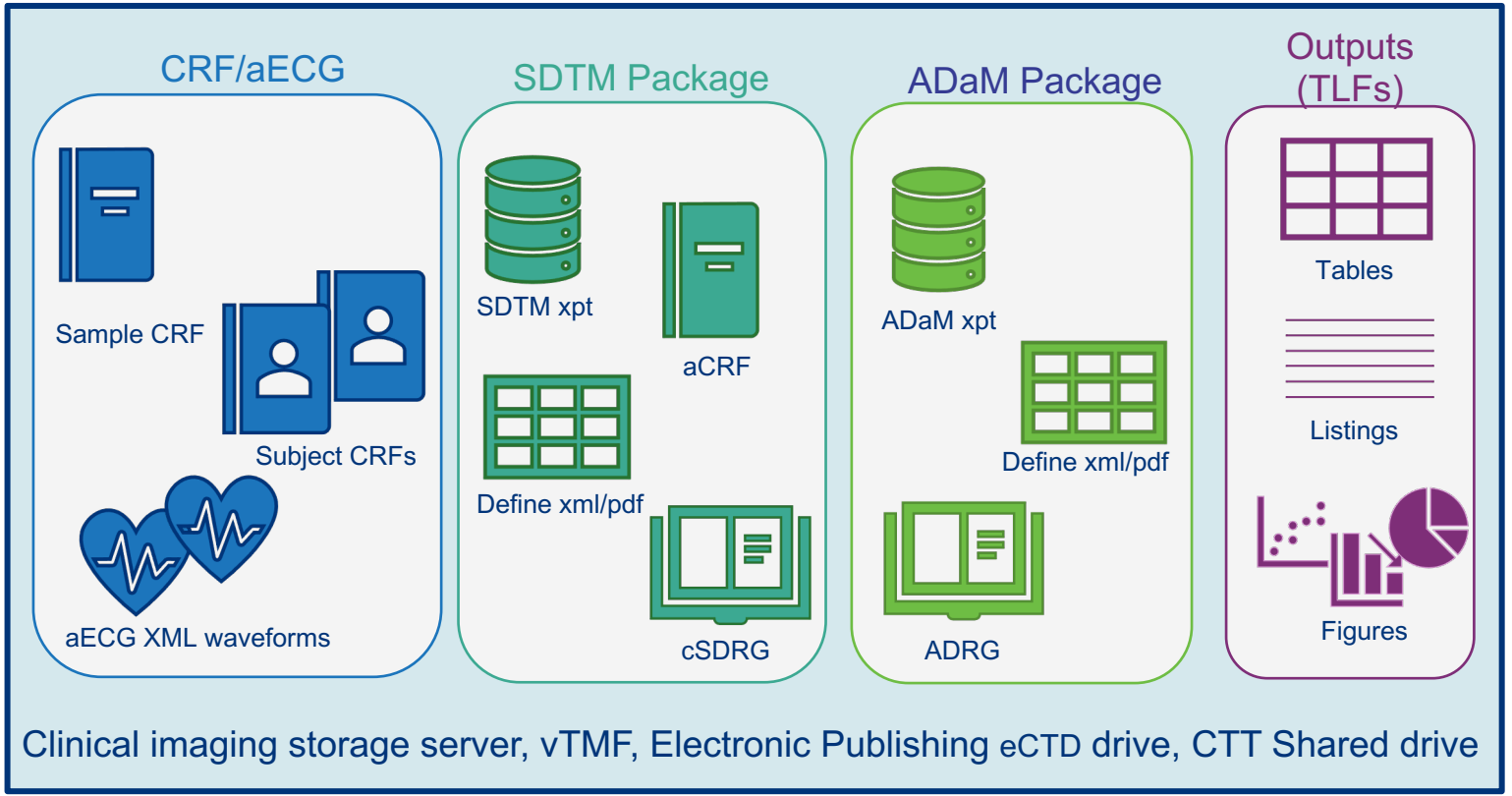
Follow processes/pre-specified rules & instructions

Scope

CHECK
Ongoing
&
Final

SEND NOTIFICATION
verification results

DELIVER
Final



TMF= Trial Master File
CTT= Clinical Trial Team

eCRF & aECG RPA BOT

SDTM and ADaM e-Submission RPA BOTs

TLFs Consistency BOT

TLFs delivery and re-delivery BOT

What our RPA BOTs do not do

BOT **does not manipulate** the content of the submission files.

BOT **does not replace any established Standard Operating Procedures**.

BOT **does not replace Risk-Based Quality Review** of deliverables

BOT **does not replace any compliance validations** (e.g. Pinnacle 21, Janssen proprietary checks) performed on study data/metadata during trial conduct.

BOT **does not replace the spot-checking** that ensures that hyperlinks were correctly built (that they point to the intended location), however, it does check if hyperlinks are broken (that they do not point to any location).

Benefits of our RPA BOTs

Extensive Automated Verifications of file formatting and file structures of **ALL** submitted files – both during trial conduct and final stage.

As a result, **increased quality confidence**.

Automated Validation for Submission Compliance: for issues identified during the validation, a report will be generated and sent to the validation requester.

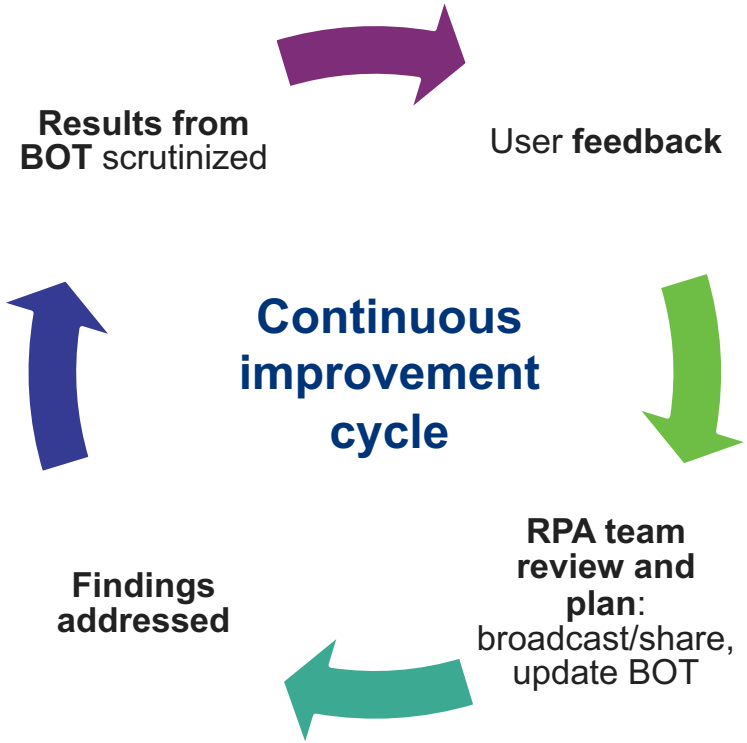
Assurance that the submission preparation process was followed **consistently**. Minimal chance of getting questions from HA on these deliverables during the submission review, that can result in a potential delay in drug approval.

Automated folder structure creation and delivery to the publisher or archival (when passes validation).

Time reduction for verification and delivery of these files: manual work reduction, faster overall QC/delivery time, human error reduction.

RPA BOT Support and Maintenance

- **RPA team**: tech support, SMEs
- **Guidance documents**: SOPs, Job aids, checklists, guidance on interpretation of validation results
- Virtual business support **help desk**
- Focused training, experience sharing and **Q&A** sessions



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The Global Healthcare Data Science Community

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