



Experience with implementing eCTD

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Benefits of implementing eCTD

- Efficiency and Speed
- Data Accuracy
- Version Control
- Cost Savings
- Global Standardization
- Searchability and Accessibility
- Real-Time Updates
- Digital Signatures
- Improved Communication
- Electronic Archiving
- Reduced Environmental Impact
- Global Acceptance

Key Considerations

 Regulatory Requirements & Regulatory Guidance

 Training and Skill Development & Standard Operating Procedures & Change Management

 IT Infrastructure & Software and Tools

 Interoperability

 Data Security

 Communication with Industry

 Performance Metrics

 Continuous Improvement

Initial Activities



Key to successful transition was to have Industry engagements and to allow reasonable time for applicants to transition (i.e. investment in tools and resources for the conversion of formats for old and new applications)



Create contact sessions with Industry to socialise the updated Guidelines



Created an opportunity for Industry to Pilot the process and refine process and guidelines – this allowed us to ensure all information was clear and well understood and easy to implemented during main roll-out.



Initial eCTD submissions were made via USB devices in 2019 ---- this was rapidly changed with the advent of COVID-19 – from 1 Aug 2019.



Investment in additional infrastructure and network configurations completed between April 2019 and July 2019 to all submissions to be channelled through SFTP portal with each applicant have been issued with unique credentials.

SAHPRA's eCTD Roadmap

High level key challenges

Challenges	Resolutions
<ul style="list-style-type: none">• CDs/USB incorrectly labeled or not readable	Established an online file submission mechanism via File Transfer Protocol (FTP) with an automated virus scan complimented with file format rules.
<ul style="list-style-type: none">• Virus checks/scan - huge administrative overhead	
<ul style="list-style-type: none">• Corrupted/incomplete file transmission due to network issues at either end – this also would impact on the individual file MD5 checksum.	Resulting in resubmission of the dossier.