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The increasing volume of applications received by NAFDAC coupled with dossier review administration issues, resource constraints, and outdated manual document management systems resulted in the development of a significant backlog in medicine registration and prolonged review timelines

NAFDAC management has been working to increase resources and improve its processes by injecting quality into its regulatory review process and along with other initiatives and interventions.

One of such initiatives is automation of dossier review processes that will pave way for efficient and transparent, streamlined review processes, coupled with increased consistency, evidence-based decision-making practices that will reduce timelines and improved customer satisfaction in their dealings with NAFDAC **(Dossier Management System)**
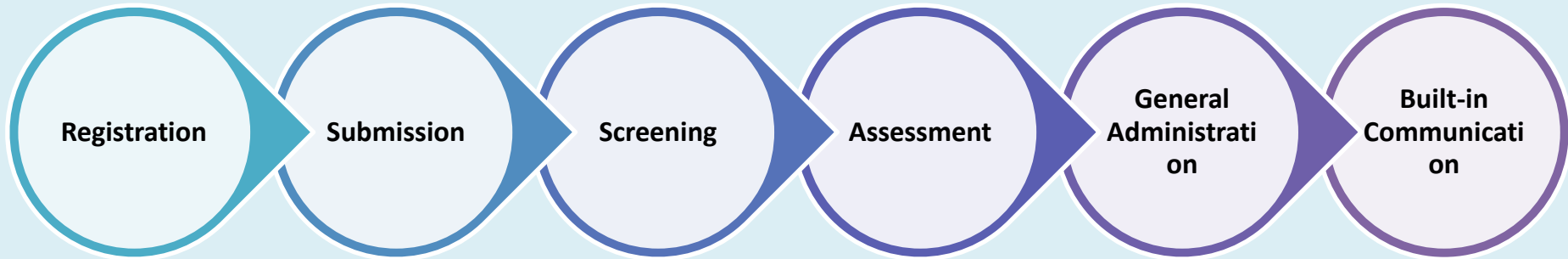
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MODULAR ARCHITECTURE

- Register Applicants
- All information will be sent to verified email Address

- Ensures everyone Follow the rules
- Real time Communication via verified email

- Management of Users, Security, Roles/Access, Audit Trail, upgrades etc.

Registration → **Submission** → **Screening** → **Assessment** → **General Administration** → **Built-in Communication**

- Submission Follows CTD Standard and follows the Guidelines strictly

- Simultaneous Assessment by Quality, API and Safety/Efficacy Units
- Real time Communication via verified email

- All messages are stored in-line with all activities on each Application

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The Dossier Management Platform

Tracking Applications on Dossier Management Platform

BENEFITS OF DOSSIER MANAGEMENT PLATFORM

- State-of-the-Art platform that automates/digitizes all the tasks in the Dossier Management department

- Provide end-to-end paperless processing

- Easy to follow CTD folder structure standard (Bookmarking and Structured file upload)

- Real time tracking of activities on application by applicants

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BENEFITS OF DOSSIER MANAGEMENT PLATFORM

- Performance monitoring features for dossiers and users

- Notification when dossier window is opened

- Immediate Feedbacks to Dossier Owner (via email)

- Email support channel

- Reduce administrative workload by 35% internally

- Observe Confidentiality, Integrity and Availability protocol

  backed up with SLA with our service provider

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CONCLUSION

The automation of Dossier Management system when fully functional? will increase consistency, streamline processes, transparency, accountability, evidence-based decision-making practices that will reduce timelines and improved customer satisfaction.

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THANK YOU

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