

OUTLINE



INTRODUCTION



MODULAR ARCHITECTURE



DOSSIER MANAGEMENT PLATFORM



TRACKING APPLICATIONS IN DOSSIER MANAGEMENT PLATFORM



BENEFITS OF THE DOSSIER MANAGEMENT PLATFORM



CONCLUSION



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NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

INTRODUCTION

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volume of applications received by NAFDAC coupled with dossier review administration issues, resource constraints, and outdated manual document management systems resulted in the development of a significant backlog in medicine registration and prolonged review timelines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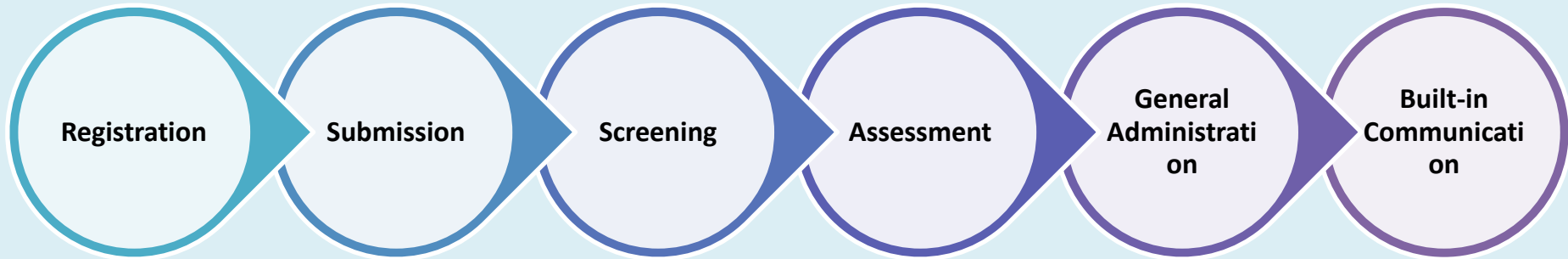
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MODULAR ARCHITECTURE

- 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.



- 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

The screenshot shows a web browser window with two tabs: "Dossier Application Form | My" and "Dossier New Registration | My". The address bar shows the URL: newwaveseecosystem-nafdac-staging-5873317.dev.odoo.com/dossier-new-registration. The browser is in Incognito mode.

The website header includes the NAFDAC logo and navigation links: Home, New Registration, Screening Report, WHO Collaborative Procedure, and Contact us. The user is logged in as "Sam Sam" and there is a "Contact Us" button.

Instructions

The operations of this Platform complies with the NAFDAC act Cap. N1, LFN 2014 and made to guidance applicants on the organization of information to be provided to the agency in seeking marketing authorization for medicinal products for human use. It also guides industry players on the expectations of NAFDAC as it concerns submission of product dossiers in CTD format. Applicants are encouraged to read these guidelines in conjunction with other relevant rules and regulations before filing a submission to the Agency.

CTD Directory Structure Option	PDF with Bookmark Option
Module 1	
1.0 Cover Letter	Upload
1.1 Table of Contents of the application including Module 1	Upload
1.2.1 Application Letter	Upload
1.2.2 Registration Form	Upload
1.2.3 Certificate of Incorporation	Upload
1.2.4 Power of Attorney	Upload
1.2.5 Notarised Declaration of the applicant	Upload
1.2.6 Contract Manufacturing Agreement	Upload
1.2.7 Certificate of Pharmaceutical Product	Upload
1.2.8 Certificate of Good Manufacturing Practice	Upload

The bottom of the screenshot shows the Windows taskbar with various application icons, a search bar, and system tray information including the date and time: 11:44 PM, 2/4/2023.



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Tracking Applications on Dossier Management Platform

Dossier Application Form | My × My Dossiers | My Website × +

newwaveseecosystem-nafdac-staging-5873317.dev.odoo.com/my/dossiers

Home New Registration Screening Report WHO Collaborative Procedure Contact us Samuel Contact Us

Home / Dossiers Sort By: Number

Number	Screening Assessment	Quality Assessment Done	Safety Assessment Done	API Assessment Done	Status
DA00003	Completed	Completed	Completed	Completed	Accepted

Useful Links

- Home
- About us
- Products
- Services
- Contact us

About us

The National Agency for Food and Drug Administration and Control (NAFDAC) was established by Decree No. 15 of 1993 as amended by Decree No. 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004 to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of Food, Drugs, Cosmetics, Medical Devices, Packaged Water, Chemicals and Detergents (collectively known as regulated products). The Agency was officially established in October 1992. Our Core Values includes

- Ensure availability of efficacious and good quality NAFDAC regulated products.
- Maintain reference laboratories of International Standards.
- Promote an effective and efficient well motivated and disciplined workforce.

Refer to <https://www.nafdac.gov.ng/> for details of all our Services and Publications

Connect with us

- Contact us
- dossiersupport@nafdac.gov.ng
- 0700-1-NAFDAC (0700-1-623322), +234(0)-1-4609750
- Powered By: Newwaves Ecosystem Limited

82° Search 23 ENG 11:45 PM 2/4/2023



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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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