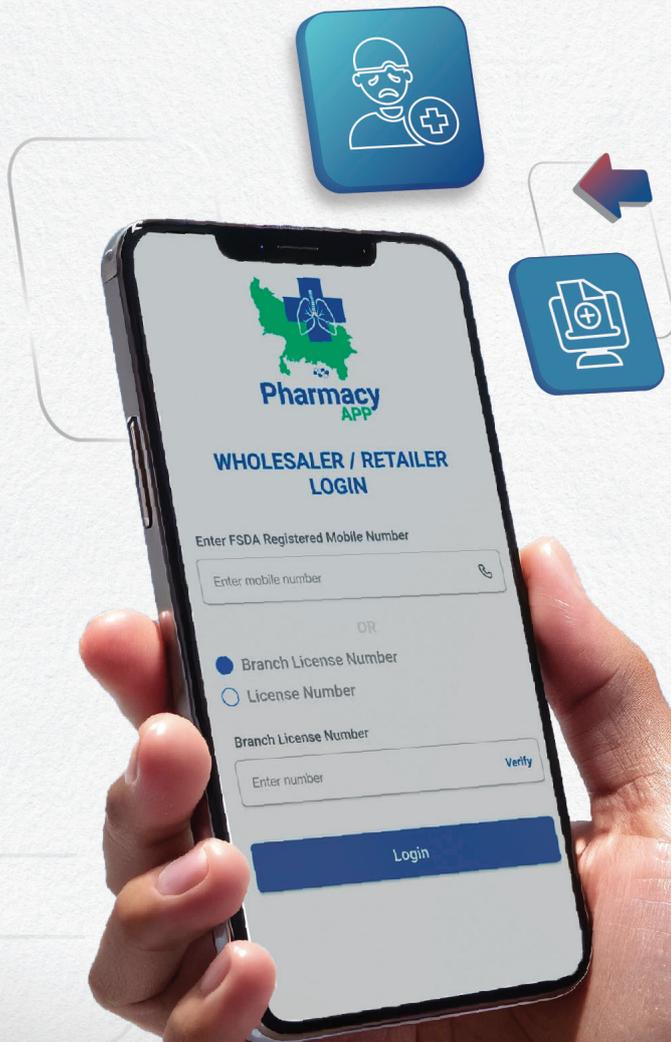


Enhancing **TB Care** through the **Pharmacy Application**



Digitising Schedule
H1 Anti-TB Drug Sales
in Uttar Pradesh

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List of Abbreviations

ABDM	Ayushman Bharat Digital Health Mission
ATT	Anti-Tuberculosis Treatment
CTD	Central TB Division
C&F	Carry & Forward
DBT	Direct Benefit Transfer
DPMU	District Programme Management Unit
FSDA	Food Safety and Drug Administration
GoI	Government of India
ICT	Information and Communication Technology
NHM	National Health Mission
NPY	Ni-kshay Poshan Yojna
NTEP	National TB Elimination Programme
STC	State TB Cell
STSU	State Technical Support Unit
TB	Tuberculosis
UP	Uttar Pradesh
UP TSU	Uttar Pradesh Technical support Unit

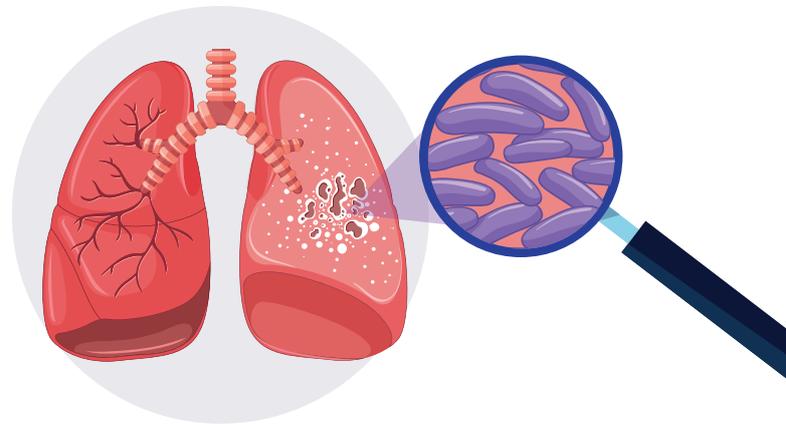
Introduction

Tuberculosis (TB) continues to pose a significant global public health challenge. India bears 26% of the global TB burden and recorded over 2.5 million cases of TB in 2023¹. The National TB Prevalence Survey highlights that more than half of the individuals with TB, irrespective of their financial capacity, access care through the private sector². Patient pathways for individuals seeking care in the private sector are often complex, involving multiple visits to different providers and resulting in delayed or missed diagnoses and high out-of-pocket expenses.

Uttar Pradesh (UP), home to 16% of India's population, reported over 0.62 million TB cases in 2023. The India TB Prevalence Survey (2019-21) estimates that UP could have close to one million individuals with active TB, revealing a significant gap in TB detection and notification³. For many individuals experiencing TB symptoms, such as a persistent cough and fever, pharmacies serve as a common first point of contact⁴. While UP accounts for approximately 33% of India's private-sector anti-TB drug sales⁵, a large proportion of

these treatments remain outside the formal notification system, highlighting the need for innovative approaches to address this challenge.

The TB State Technical Support Unit (TB-STSU) – implemented by India Health Action Trust (IHAT), provided strategic technical support to the State TB Cell (STC), UP, from March 2022. The IHAT team continues to support the state in multiple areas not limited to multi-sectoral engagement, programme design, partner coordination, diagnostics optimisation, and community-based innovations.



¹ India TB report 2024

² National TB Prevalence Survey - in India (2019-2021) <https://tbcindia.mohfw.gov.in/2023/06/06/national-tb-prevalence-survey-in-india-2019-2021/>

³ Indian Council of Medical Research; National Institute for Research in Tuberculosis; Ministry of Health and Family Welfare, Government of India; Central TB Division; World Health Organization. National TB Prevalence Survey India 2019–2021. 2022. Available online: <https://tbcindia.mohfw.gov.in/2023/06/06/national-tb-prevalence-survey-in-india-2019-2021/>

⁴ Mistry N, Rangan S, Dholakia Y, et al. Correction: durations and delays in care seeking, diagnosis and treatment initiation in uncomplicated pulmonary tuberculosis patients in Mumbai, India. PLoS One 2016; 11. doi: 10.1371/journal.pone.0160796 • Google Scholar

⁵ Arinaminpathy, N., Batra, D., Maheshwari, N. et al. Tuberculosis treatment in the private healthcare sector in India: an analysis of recent trends and volumes using drug sales data. BMC Infect Dis 19, 539 (2019). <https://doi.org/10.1186/s12879-019-4169-y>. BMC Infectious Diseases

Executive Summary

Anti-TB drugs are life-saving, essential medicines listed under the National TB Elimination Programme (NTEP). Given the growing threat of drug-resistant TB, quality control, secure dispensing, and strict record-keeping are critical. Despite mandates requiring private pharmacies to report sales of Schedule H1 anti-TB drugs, reporting remains incomplete and inconsistent, undermining data quality and limiting the ability to identify all individuals accessing TB treatment in the private sector. The notification of individuals receiving TB treatment is not merely a legal mandate, but also serves to address the ongoing prevention and care needs of the individual and family through public health actions.

To address the notification gap, IHAT, in consultation with the STC and the Food Safety

and Drug Administration (FSDA), pioneered the Pharmacy Application. The Pharmacy Application is both web and mobile-based application that digitises patient-linked sales of anti-TB drugs from private pharmacies in compliance with Schedule H1 regulations⁶. The application integrates with the FSDA licensing database and cross-references data with Ni-kshay⁷, enabling strengthened surveillance, proactive TB case identification, and timely public health follow-up.

The Pharmacy Application was piloted between August 2024 and June 2025 in an urban area of Lucknow and received a positive response for state-wide scale-up across all 75 districts of UP. During the pilot, around 20% of participating retail pharmacists recorded sales of anti-TB drugs. In the pilot analysis, on average, each of these retail pharmacist reported sales to about 15 individuals with TB, of whom nearly one-third had not been previously notified in Ni-kshay. If this finding is extrapolated to the state's 1.67 lakh registered retail pharmacists, assuming at least 10% of them sell anti-TB medications, the potential to identify and reach individuals with TB who have missed notification despite being on TB treatment, could be approximately 1,00,000.



⁶ Refer to Background and context section: Role of Schedule H1 in 2014—an amendment to the Drugs and Cosmetics Rules of 1954 in TB Elimination effort

⁷ Ni-kshay- (Ni=End, Kshay=TB) is the web-enabled patient management system for TB control under the National Tuberculosis Elimination Programme (NTEP). It is developed and maintained by the Central TB Division (CTD), Ministry of Health and Family Welfare, Government of India, in collaboration with the National Informatics Centre (NIC), and the World Health Organization country office for India. Ni-kshay is used by health functionaries at various levels across the country both in the public and private sectors, to register cases under their care, order multiple types of tests from labs across the country, record treatment details, monitor treatment adherence, and to transfer cases between care providers. It also functions as the National TB Surveillance System and enables reporting of various surveillance data to the Government of India

Addressing the Need for a Digital Tool

Pharmacy Application to Enhance TB Notification in the Private Sector

Despite legal mandates for reporting Schedule H1 anti-TB drug sales, private pharmacies and retail pharmacists lack the tools and infrastructure to maintain and submit these records to the concerned authorities. The paper-based registers used by most retail pharmacists are often incomplete, poorly maintained, or discarded before the mandated three-year retention period ends. Thus, it becomes challenging for NTEP staff to collect, analyse, and act upon information on TB drug sales. Limited enforcement and the absence of formal systems for data collection and verification further hinder compliance, despite the legal provisions for penalties under the Drugs and Cosmetics Act. This fragmented system undermines surveillance, and many individuals living with TB remain invisible to the health system. This has been one of the key causes of significant underreporting and data gaps in the national TB surveillance system (Ni-kshay). Consequently, unnotified individuals with TB, especially from the private sector, remain outside the formal health system, increasing the risk of missed diagnosis, incorrect treatment, continued disease transmission, and lack of access to critical government support, including the

Ni-kshay Poshan Yojana (NPY) (INR 1,000 per month), comorbidity screening, bacteriological confirmation, drug-resistance testing, follow-up adherence support, and contact evaluation with TB preventive treatment for vulnerable contacts. A streamlined and efficient system to track drug sales, identifying TB cases which are not notified and facilitate essential government support services will accelerate India's TB elimination efforts.

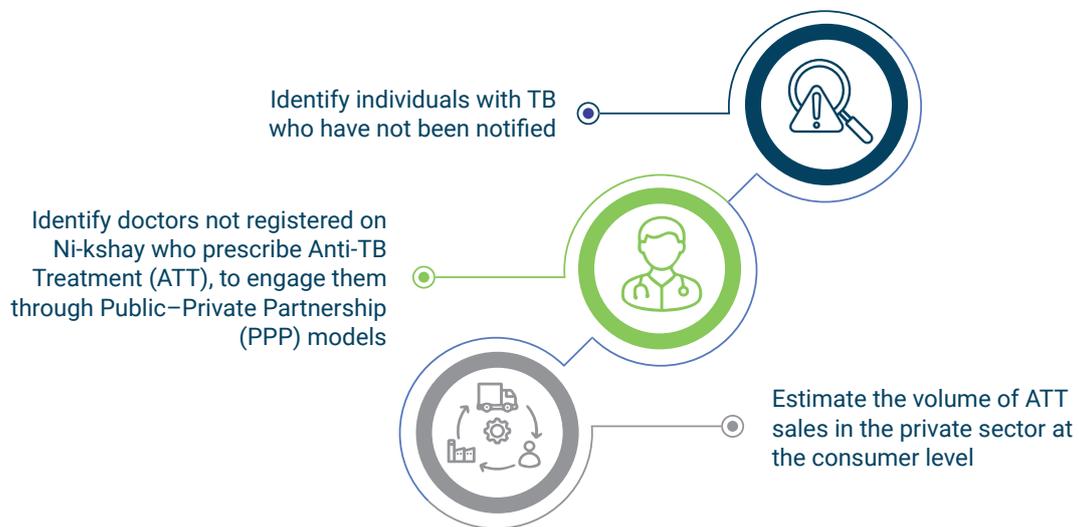
The Pharmacy Application aims to overcome the challenges of manual collection and management of anti-TB drug sales data in UP. This intervention introduces a centralised, paperless platform to automate data collection, integrating with the FSDA license database, and has the potential to identify those missed during notification and minimise treatment dropouts. By digitising and standardising the capture of H1 drug sales (Government Order No New Delhi 30 August, 2013 <https://dcaodisha.nic.in/sites/default/files/Schedule%20H1%20Drugs.pdf>), the application ensures accountability for every dispensed tablet, while also providing an opportunity to estimate the TB burden through the last-mile point of sales.

Objectives of the Pharmacy Application

The Pharmacy Application is a digital platform with both web-enabled and mobile versions to digitise the tracking and reporting of anti-TB drug sales across private pharmacies in UP.

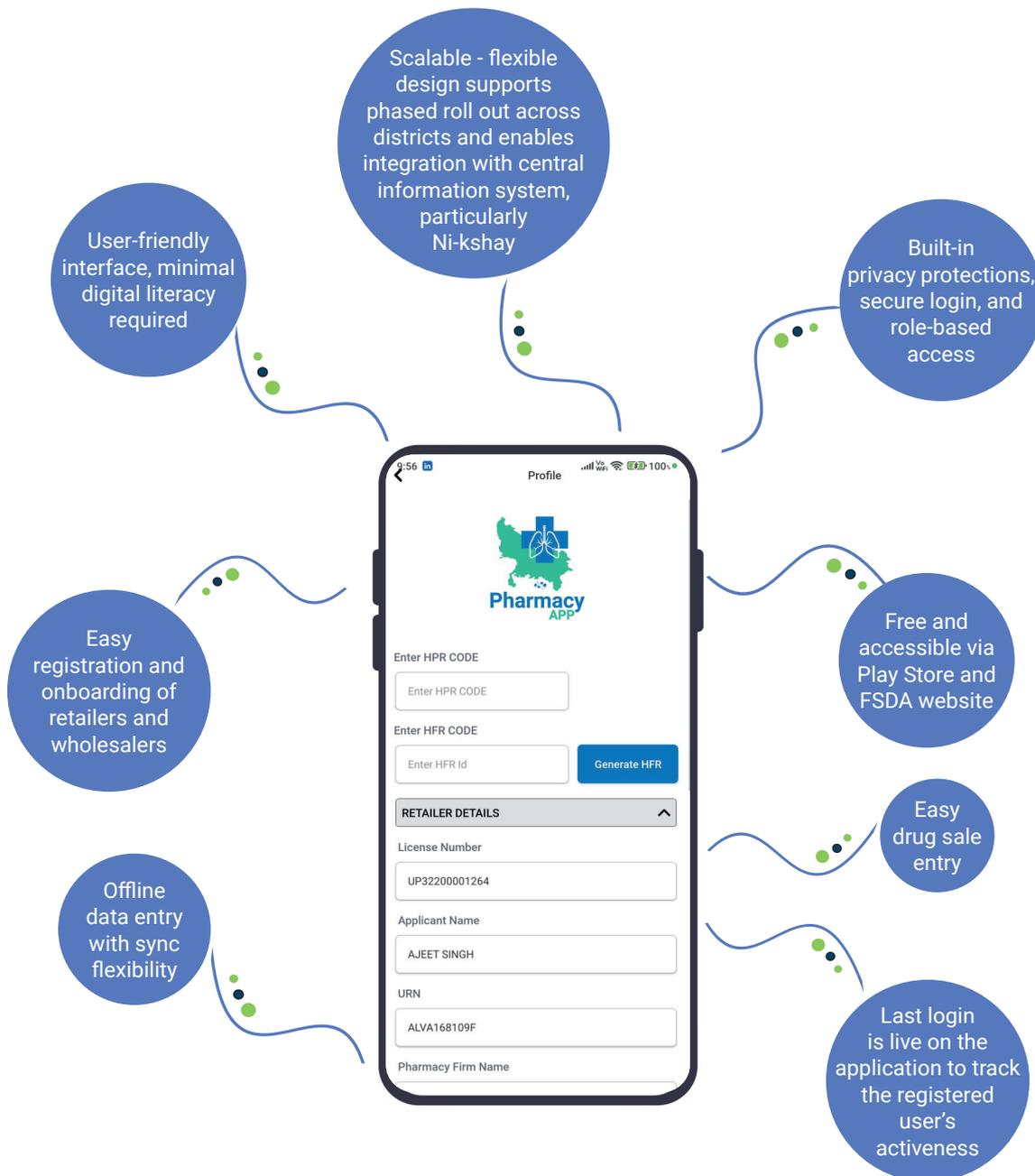
The application is designed to capture Schedule H1 drug sales, in line with the Government of India's 2014 amendment to the Schedule H1 notification.

The objectives of developing the application are:



Key Features of the Pharmacy Application

Figure 1: Key Features of the Pharmacy Application



Application Development, Interface Design and Vendor Selection

India Health Action Trust's team, FSDA, STC, the NHM-UP and the UP TSU jointly developed the Pharmacy Application. The conceptualisation, design, and development process commenced in July 2023.

The ICT team focused on transforming the programme requirements into a workflow-based system that is user-friendly, technically

robust, scalable, reliable, and high-performing. The application design accommodates all user roles, including local pharmacies, large drug distributors, and administrative departments such as FSDA, NHM, and STC. The FSDA has now taken ownership of the Pharmacy Application and hosts the information on their server.

Figure 2: Snapshot of Pharmacy Application (Anti TB Drug Monitoring System on FSDA UP website)

The screenshot shows the FSDA Government of Uttar Pradesh website. At the top, there is a navigation bar with links for Feedback, Contact, Sitemap, and social media icons. A search bar is located on the right. Below the navigation bar, there is a main menu with links for Home, About FSDA, Public Awareness, Acts & Rules, Media Center, RTI, G.Os / Notifications, and Licences / Registration. The main content area features a news item titled "UP Pharmaceutical and Medical Device Policy, 2023" with a "Click here to View" link. Below this, there are two profile cards: one for Yogi Adityanath, Hon'ble Chief Minister, Uttar Pradesh, and another for Shri Dayashankar Mishra "Dayalu", State Minister. The page also includes several service links such as "Online Food Registration and Licensing", "Department Official Login", and "Apply online for New Drug/Cosmetics and Certificates". A "Complaint/Grievance Redressal Cell" section provides contact information for the Food and Drug Sections. At the bottom, there is a "News & Events" section with links for Press Releases, BRAP, and Verify DL, and a banner for the "Anti-TB Drug Monitoring System".

End-to-End Process Flow of Pharmacy Application

The workflow of the application outlines the complete process, that is, from a TB patient purchasing medication at a pharmacy, to the case being notified on the Ni-kshay platform,

verified, and linked to appropriate TB care and benefit schemes through coordinated action between pharmacists and the NTEP team.



1 Patient Purchase: TB patient visits the pharmacy to buy anti-TB medication.

2 Pharmacist Login: Pharmacist logs into the application.

a. Patient Details are added:

- If already registered – search by name or mobile number.
- If new – enter patient details manually.

b. Prescriber Information Added:

- Select from the dropdown list of practitioners.
- If not listed – manually enter name.

c. Prescription Entry:

- Pharmacist chooses the drug combination from the system.
- Drug purchased by the patient entered.
- If a patient's relative collects the medicine on their behalf, their details are also recorded.



Dashboard Monitoring: District NTEP team reviews real-time sales data via the built-in dashboard in the application.

Cross-Verification: Data is matched with Ni-kshay to flag unnotified TB cases.

Follow-up on Missed Cases:

- a. NTEP staff visit the concerned practitioner.
- b. If a practitioner unregistered → made to register on Ni-kshay.
- c. Practitioner enters missed cases into Ni-kshay.

Case Linkage:

- a. Ni-kshay ID updated in the application.
- b. NTEP team follows up with notified individuals to link them to TB care and benefits.

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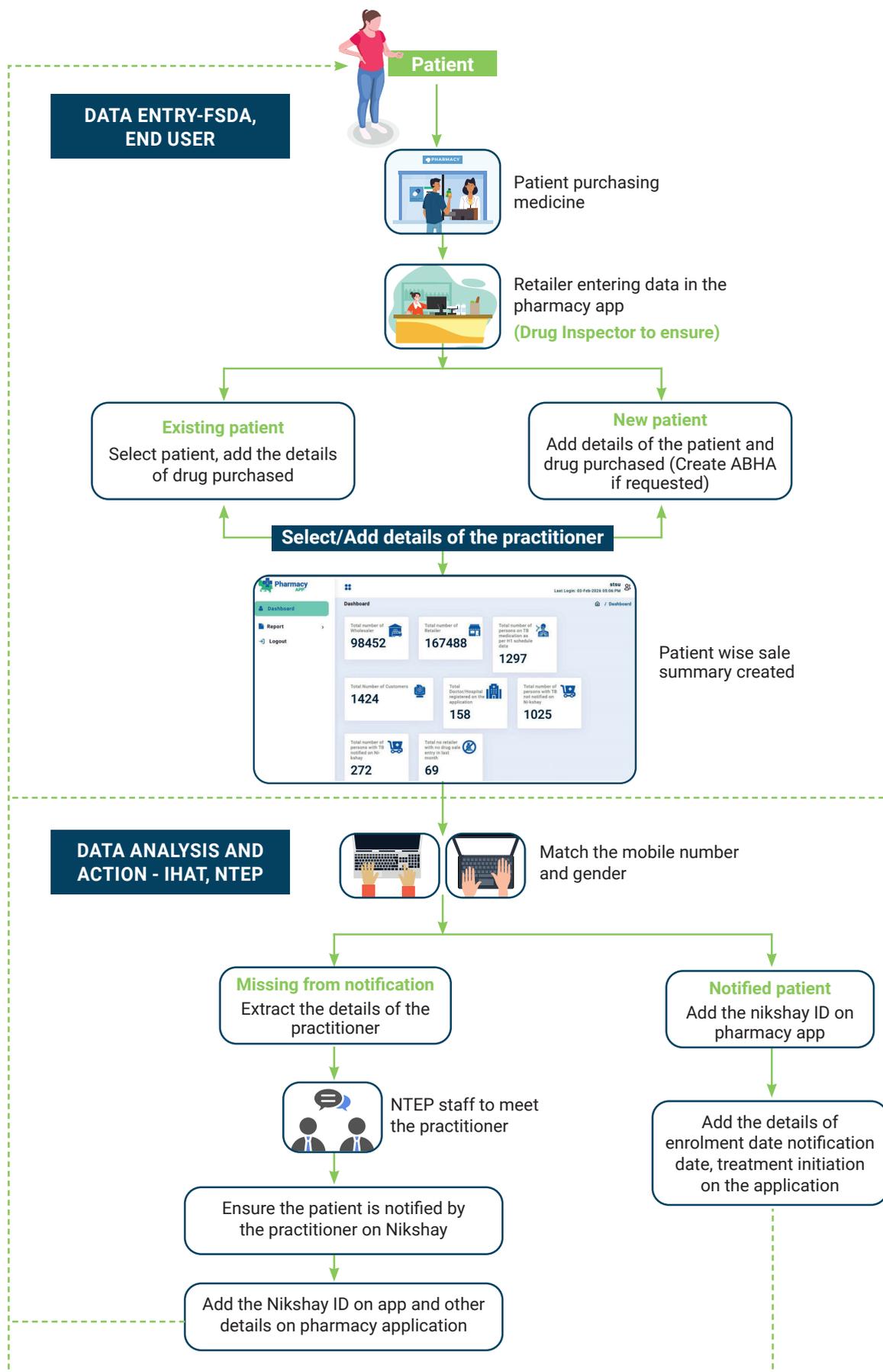
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Figure 3: End-to-End Process Flow of Pharmacy Application



Process of Pilot and Scale-Up

The pilot and scale-up of the Pharmacy Application in UP followed a phased, structured approach involving development, approvals, piloting, feedback, training, hosting, and expansion.

 Timeline	 Key Process	 Key Milestones
July-December 2023	Application development approvals in consultation with FSDA, NHM -UP, STC-UP & UPTSU.	The Pharmacy Application was developed.
January-March 2024	<ol style="list-style-type: none"> 1. Application presented to the Mission Director (MD), NHM, Lucknow, UP. 2. Directives to provide support for the pilot were shared with District Magistrates (DMs), Chief Medical Officers (CMOs), and District TB Officers (DTOs) by the MD, NHM on 13 February 2024. 	Approval from the MD, NHM for the pilot in five districts of UP (Lucknow, Jhansi, Sonbhadra, Ghaziabad, and Gorakhpur).
April-May 2024	Coordination with FSDA and the State DATA Centre, with support from the IHAT team, for server acquisition.	The application went live on the FSDA website in April 2024.
June - July 2024	<ol style="list-style-type: none"> 1. Orientation of Drug Inspectors and DTOs from the five pilot districts on 14 June 2024. 2. Training sessions for wholesalers and retailers in Aminabad, Dr Ram Manohar Lohia (RML) Hospital, King George Medical University (KGMC), and Mahanagar, Lucknow. 	A total of 228 personnel equipped, including wholesalers, retailers, FSDA and NTEP staff, through both online and in-person training sessions.
August - September 2024	<ol style="list-style-type: none"> 1. Troubleshooting issues at the Carry and Forwarding (C&F) agency (Lupin) related to accessing the Pharmacy webpage, and orientation of Lupin ground staff at the depot in Lucknow. 2. Pilot initiation in Lucknow. 	Pilot initiated in Lucknow in August 2024.

Timeline	Key Process	Key Milestones
October 2024	<ol style="list-style-type: none"> 1. Work in progress to resolve issues in the Application Programming Interface (API) integration between the FSDA license registration portal and the Pharmacy Application for user registration. 2. Issuance of directives by the FSDA Commissioner to Drug Inspectors. 	Issuance of directives by the FSDA Commissioner to Drug Inspectors across all districts of the state.
November - December 2024	<ol style="list-style-type: none"> 1. Database for licenses shared by FSDA. 2. Training of wholesalers, retailers, and NTEP staff initiated. 3. Data flow initiated on the application. 	Data flow in the application began, enabling retailers, wholesalers, and C&F agents to enter data.
January - June 2025	<ol style="list-style-type: none"> 1. Hiring of a Field Officer to cover the Lucknow area for registration. 2. Pilot completed in Lucknow, and approval obtained from FSDA to launch the application in all districts in campaign mode. 	Successful completion of the pilot in Lucknow.



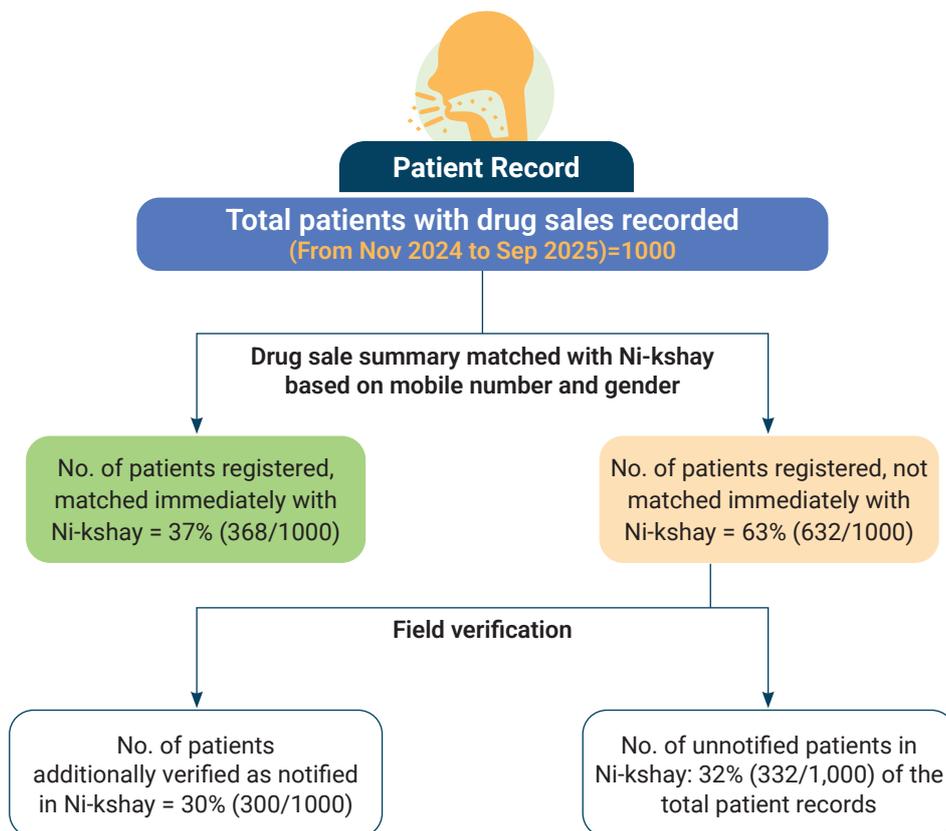
Training Programme of Pharmacy Application for wholesalers, retailers, and NTEP staff, chaired by State TB Officer in Lucknow on 24 July 2024 and 25 July 2024

Results

The pilot implementation of the Pharmacy Application in an urban area of Lucknow demonstrated significant potential in bridging the public-private gap in TB surveillance. A total of 225 registered users (one C&F agent, 35 wholesalers and 190 retailers) were registered on the application. The drug sales are recorded at the C&F level, wholesale level, retail level in the application. And patient-level

data is extracted from retail sale reports. Of the 190 retailers, 75 retailers entered data on anti-TB drug sales, while the remaining retailers recorded zero sales. The process flow and results of drug sales data analysis for identifying unnotified TB patients using pharmacy application and Ni-kshay (November 2024–September 2025) is depicted in Figure 4.

Figure 4: Algorithm depicting the process and results of drug sales analysis to identify unnotified TB patients through linkage with Ni-kshay



ATT drug sales were recorded **3329** times, involving **32** distinct drug formulations and accounting for **81,972** tablets dispensed.

Additionally, the pilot provided valuable insights into private-sector ATT drug dispensing patterns, which reflect real-world usage trends.

Extrapolating from the data, of the total 1,67,487 retailers registered in the state, it is estimated that about 16,748 (10%) may be selling ATT. If each of these retailers sell ATT to at least seven (214/65X12/6) non-notified individuals on TB treatment per year, the application has the potential to identify approximately ~1.2 Lakh individuals on TB treatment who have been missed in the notification.

These findings underscore the critical role of digital tools in strengthening TB surveillance across public and private health systems. By identifying active TB cases that were missed in notification and mapping drug-dispensing patterns across geographies, the Pharmacy Application not only helps close critical notification gaps but also lays the foundation for state-wide scale-up of digital reporting systems under the H1 Schedule framework.

Way Forward

The pilot has established both the feasibility and transformative potential of the application to expand engagement with private pharmacists and clinicians, and strengthen accountability in the sale of anti-TB drugs.

Building on the learnings and the demonstrated success of the pilot phase, the Pharmacy Application is now prepared for state-wide scale-up across all 75 districts of UP. During scale-up, implementation support will be

required to enhance the application based on the feedback received from implementation, integration with other public health modules, stakeholder training, the setting up of a helpdesk/call centre, a robust monitoring and evaluation framework, and a surveillance dashboard that provides the right information at the right time. The FSDA department in UP will bear the cost of application maintenance and periodic security audits.

Testimonial on the Pharmacy Digital Application

The Pharmacy Application marks a significant milestone in leveraging digital innovation for public health surveillance. As the technical support partner for the State TB Cell, IHAT has worked closely with the Food Safety and Drug Administration and NHM to conceptualise, design, and operationalise this pioneering tool. The collaboration has demonstrated how technology and partnerships can bridge long-standing gaps in TB notification, especially from the private sector. The success of the pilot phase reinforces the value of data-driven approaches and multi-sectoral coordination in realising the vision of a TB-free Uttar Pradesh.

Assistant Commissioner,
Food Safety and Drug Administration (FSDA), Uttar Pradesh

As a pharmacist, I truly appreciate the Pharmacy Application developed to digitise Schedule H1 drug sales. Earlier we maintained TB-related records manually in registers, which took time and carried the risk of data loss. Now we can easily enter patient details directly into the system, and all H1 drug sales records are stored safely. The application is simple, user-friendly, and has made our work much smoother. It has improved transparency and made it easier to support TB notification and monitoring, helping pharmacies like ours contribute to TB elimination efforts in Uttar Pradesh.

Chemist,
Medical Store, Lucknow, Uttar Pradesh

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