



ProductDossier[®]


Project Management First



TouchBase Dossier Management (Pharma)

TouchBase

Dossier Management (Pharma)

- 1 Dossiers - the weak link in drug development
 - 2 Key Challenges
 - 3 Lost Opportunities
 - 4 TouchBase Capabilities
 - 5 TouchBase Differentiators
 - 6 TouchBase Business Value
 - 7 TouchBase Modules
 - 8 TouchBase Glimpses
- 



Dossiers - The weak link in drug development

Innovations in biomedical sciences and technology fuel the opportunity to transform R&D for new-drug development holistically - 500 days faster, better tailored to patient needs, and 25 percent cheaper.

Studies indicate Dossier Management to be one of the weakest links in the race against time and costs.

Achieving an accelerated-timeline goal requires embedding a host of solutions and platforms in dossier-filings teams that span both technology solutions and knowledge-driven assets.

Pharma Dossier Challenges

1

Manual and inefficient dossier creation.

2

Email-based cross-functional team review.

3

Immature dossier management processes.

4

Changes and versions lack audit trail.

5

Weak documentation access controls.

6

Vulnerable to privacy and security threats.

7

Weak dossier life cycle – creation to disposal.

8

Higher cost of document management.

Pharma Dossier Lost opportunities

Questionable dossier
data integrity



Sub-par dossier quality

High cost of dossier
management



Delayed legal and
compliance approvals

Lost drug patents and
associated revenues



TouchBase Capabilities

Extremely configurable solution to –

- Your industry
- Your products & services
- Your dossier management
 - Standards, compliance, & regulations
 - Business processes
 - Workflows
 - Decision-making protocols

Dossier Templates

- Create templates based on country, drug, etc.
- New Registrations, Renewals, and Variations

Track Dossier workflow till regulatory approval.

Dossier Generation

- Generate combined dossier in Word or PDF
- Send additional / changed documentation.

Semi-Products

- Track all dossiers
- Auto alerts for expiry, due dates, etc.

Dossier Project

- Execute multiple dossier projects
- Track dossier projects
- Link to drug development projects.

Dossier Documentation

- Create dossiers
- Link documents from standard document library
- Collaborate for document preparation
- Manage multiple versions
- Workflow-based document approval.

Dossier Queries

- Define query workflows
- Track internal and external queries

Capture Dossier Registration Details

TouchBase

Common Capabilities



Permissions & Access Controls



Analytics



Dashboards



Alerts & Notifications



Social Collaboration



Mobile Access

TouchBase System Integrations



TouchBase Differentiators

1 *Designed for “your” industry, drug/project type, dossier approach, standards, and business processes.*

2 *An end-to-end solution that addresses all the dimensions of dossier management*

3 *Seamless integration with other enterprise applications*

4 *95% configurable; less than 5% customization*

5 *Completely digitized dossier landscape*

TouchBase Business Value

- 1 Completely digitized dossiers.
- 2 One version of dossier truth.
- 3 Swift and data-driven decisions.
- 4 Lower cost of dossier management.
- 5 Completely access controlled.
- 6 Totally secure.

TouchBase Modules



Dossier
Management



Project Management



Project Financials
Management



Opportunity
Management



New Product
Development



Project Resources
Management



Project Quality



Timesheets & Leave
Management



Project
Documentation



Project Procurement



Utilities



Social Collaboration

TouchBase Glimpses

Dossier List

Sr.No.	Dossier No	Title	Registration Type	Region	Country	Actions
1	DOSR0022	Pharma 01	New Registration - API	US	US	
2	DOSR0021	Pharma 01	New Registration - API	US	US	
3	DOSR0020	Pharma 01	New Registration - Formulation	US	US	
4	DOSR0017	ASHIALBEN 2500 /3000 /3750	New Registration - API	US	US	
5	DOSR0016	COZASH 750	New Registration - API	US	US	
6	DOSR0015	ASHIALBEN 2500 /3000 /3750	New Registration - API	US	US	
7	DOSR0014	ASHIALBEN 2500 /3000 /3750	New Registration - API	US	US	
8	DOSR0013	Omicortal	New Registration - API	US	US	
9	DOSR0011	B-Complex	New Registration - Formulation	US	US	
10	DOSR0010	Crosin 50 mg	New Registration - Formulation	EU	Croatia (HR)	

Dossier Index

Dossier Index		Documents	WorkFlow	Registration Details	Query Points		
S.No.	Name	Actions	Doc Name	Assignee	% Complete		
				Assignee	Target Date	Status	
-	Dossier_DOSR0013						12
1.1	GLP certificate		GLP Certificate 01.pc				100
- 1.2	Clinical study report						
1.2.1	Fasting State				03-03-2021		100
1.2.2	FED state		FastingState.pdf		03-03-2021		0
1.2.3	Steady State						0
1.3	Bio-analytical report		Bioanalytical Report				100
+ 1.4	Manufacturer-Drug Product						
+ 1.5	Labeling						
+ 1.6	Package Insert						
+ 1.7	Other Document						
1.8	License of Production or Import						0



ProductDossier®
Project Management First

ProductDossier Inc.

45, Prospect Street,
Cambridge, MA 02139, USA
+1 (508) 517-6440

E-mail: sales@productdossier.com

India Office

Timeless Building, 2nd floor, 209, 1B/1A,
Range Hills, Pune – 411020, INDIA
Tel: +91 98902 91424 / +91 76209 00525

Website: www.productdossier.com

TouchBase is ready
to empower your
teams with a 100%
digitized dossier
management landscape.
Are You?