ADD Regulatory: Elevator Pitch

ADD Regulatory Platform uses state of art technologies like Artificial Intelligence, mobility, and blockchain to automate the regulatory processes, search & analysis of large set of regulatory data, and create regulatory documents, to enable faster & in compliance drug registration.

The Platform uses smart search engine combined with intelligence hub that improves compliance, operational efficiency and enables taking informed strategic decisions.

ADD Regulatory: Industry Challenges & TCS Offers

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Industry Challenges

Siloed & old-fashioned RIM solutions*

- Traditional RIM systems maintain data in silo with low adoption of new technology
- Limited use of previous data and learnings
- Manual regulatory document writing, limited reuse of data/templates

Fragmented & inefficient regulatory processes

- Several actions on email and paper, limited automation
- Inefficient oversight and tracking of regional requirements and procedural differences
- Inefficient mechanism to identify local or regional label discrepancies

Inefficient interpretation and data complexity

- Inability to interpret & connect external big data sets (e.g. product approvals, guidelines)
- Inability to draw meaningful outcome from internal data and minimal reuse of historical HA responses ~~data~~

ADD Regulatory

- Unique Plug and Play model to address gaps in traditional RIM* system and adoption of AI/Cognitive and Automation tools
- Smart search engine combined with intelligence hub that interprets user query and draft responses
- Automation document writing and re-use of data from previous documents

- Workflow framework coupled with alerts and notifications
- Leveraging intelligent automation in regulatory operations
  - Enabling automation like redaction, data anonymization etc.
  - Enabling automation in document reviews, formatting etc.
- AI enabled automation to identify discrepancies between local and central labels

- Use AI and analytics to enable collection and interpretation of big data sets and increase regulatory intelligence
- Leveraging cognitive technologies for Health Authority Query's, enabling quality reference search right first time extending re use of data and reducing overall response lead time.

*RIM - Regulatory Information Management

ADD Regulatory: Summary

RE-INVENT REGULATORY ACTIVITIES TO IMPROVE COMPLIANCE, REPORTING AND OPERATIONAL EFFICIENCY AND TO ENABLE INFORMED STRATEGIC DECISIONS AS AN EXTENSION TO YOUR RIM* BOUNDARY

	Integrated tracking & oversight	Automated regulatory activities	Regulatory Intelligence hub	Accelerated regulatory document creation**
	• Integrated & actionable regulatory processes (e.g. publishing, aggregate reporting) incl. Mobile Application • Automated alerts and notifications	• Intelligent redaction and data anonymization • Automated review/QC and formatting of regulatory content** • AI enabled Label discrepancy identification**	• Repository of various internal and external regulatory data allowing meaningful oversight using analytics • Creation of HA Response to Query (RTQ) using internal & external data • Smart search engine	• Integration & reuse of data from multiple sources • SmartAuthor documents creation (e.g. protocol, CSR, label) and reduction of submission discrepancies
Status	• Implemented for 3 top 15 pharma companies • Different features used including submission mobile app	• Document redaction is in proof of concept phase • Design was completed for data anonymization, automation in document review and formatting	• PoC ongoing to collate product info from websites • Smart search engine & RTQ available • Blockchain concept designed	• Design finalized for labelling document creation by enabling reuse of content

Co-hosted cross-pharma regulatory workshop in 1Q19, +50 participants, 12 pharma companies; 2020 workshop planning in progress.

*RIM - Regulatory Information Management

** *In development*

ADD Regulatory: Schematic Overview

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INPUT

- Internal data/RIM* Data
  (e.g. RTQs, submissions data, planning, publishing, DMS)
- External data
  (e.g. Product Approvals, Warning Letters, Health Authority sites, News/Feeds)
- Structured
- Unstructured

ADD REGULATORY

- Integrated tracking & oversight
- Automated regulatory activities
- Regulatory Intelligence hub
- Accelerated regulatory document creation

OUTPUT

- Process Workflow based monitoring- User Alerts
- Easy access to regulatory information
- Automated label creation & discrepancy management
- Automated regulatory document creation
- Health Authority query response suggestions
- Mobile Application for submission tracking

**RIM - Regulatory Information Management*

ADD Regulatory: Value Statement and Stakeholder Impact

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ADD REGULATORY SUPPORTS PHARMA COMPANIES TO EXPEDITE THE PRODUCT REGISTRATION PROCESS AND HELPS PATIENTS TO HAVE FASTER ACCESS TO BETTER AND SAFER MEDICINES AND TREATMENTS

Increased efficiencies & reduced workload	• Increased Process efficiency in Regulatory by enabling better monitoring, alerts and notification • Up to 50% reduction of submission management activities. • Increased control over regulatory processes through real-time monitoring and reports.
Improved data quality and oversight	• Ability to find information that is spread across websites/health agencies leveraging technology. • Increased strategic decision towards market and type of studies through broad historical data insight (e.g. reason for rejection)
Increased user Engagements	• Easy to Access and understand information using Mobile Apps. • Easy to interpret dashboards
Faster drug registration process	• Up to 20% reduction in regulatory filing timelines due to automation and optimization in authoring .

ADD Regulatory: Customer Use Case of Top-10 Pharma Company

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Purpose/Objective

- Reduce time-consuming regulatory activities such as
  - monthly reporting /effort (75 programs)
  - program management efforts to coordinate cross functional activities & overviews/trends identification
  - Finding relevant marketing intelligence across various external websites (e.g. HAs)
- Increase reporting of KPI/metrics (currently monthly basis) and improve oversight

Outcome

- **40% reduction in monthly reporting efforts** through roll out of mobile App and portal
- **50% reduction in program management** activities by real-time tracking and notifications to users
- **20% time reduction to search info** through regulatory intelligence portal, where questions can be asked in plain English and relevant HA sites as output
- **Flexible real-time KPI/metric dashboard and reports**

ADD Regulatory: Vision & Roadmap

OUR VISION IS TO ENHANCE COMPLIANCE WITHIN THE REGULATORY ENVIRONMENT AND INCREASE OPERATIONAL EFFICIENCY & QUALITY THROUGH AUTOMATIONS

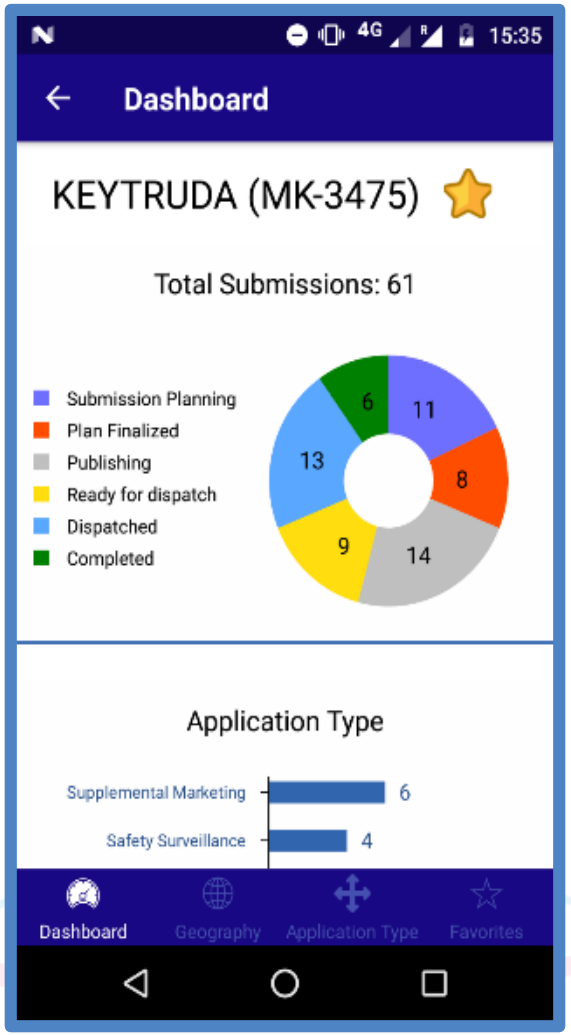
1Q20	2Q20	3Q20	4Q20
	Regulatory Intelligence Hub enhanced with: - Meeting minutes - Usability capability	Regulatory Activities enhanced with - Document formatting - Review automation - Data de-identification	
		Regulatory Intelligence Hub enhanced with - Ingest more information - System re-training	

Future plans:

- AI for Label discrepancies identification
- Blockchain for RTQ
- Regulatory Document creation (smart author) for labels
- Trace-ability of data across document in product life-cycle

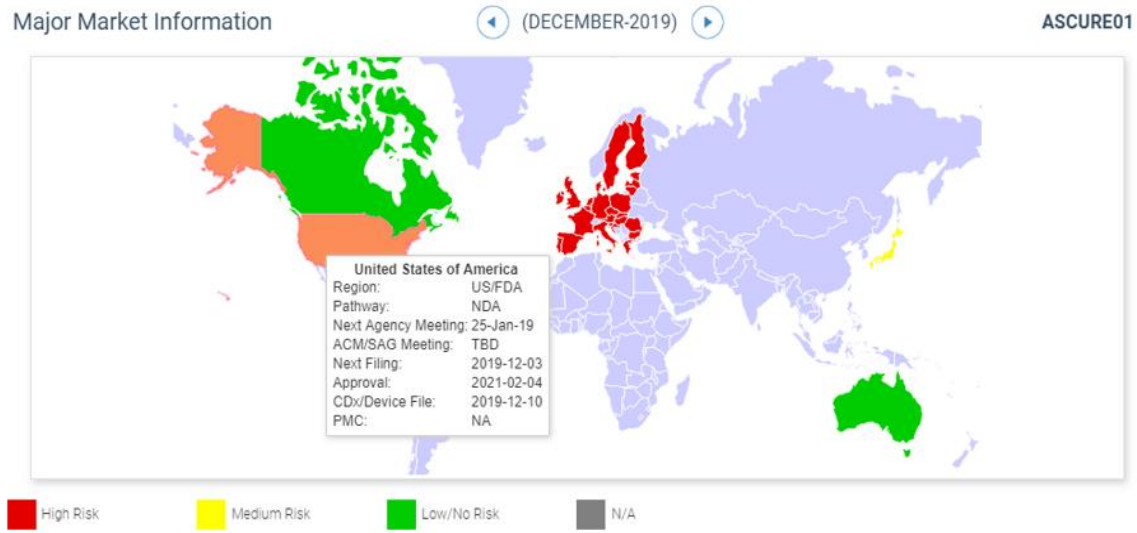
ADD Regulatory: Visuals

Submission Tracking oversight



Submission Tracker-Mobile View

Regulatory Reporting oversight



PROGRAM INFORMATION - FEBRUARY-2018

MK-3475	Therapeutic Area: Oncology
Development Phase: Phase 3	CBL (GHH): Hospital & Speciality Care
Entity: Biologic - mAb	Indication: 1L Metastatic melanoma
Pharm Target: PD1	GRT Lead: Vicki Demby
USAN/Generic Name: pembrolizumab	BRAND NAME: KeytrudaM

GOVERNING COUNCIL REVIEW

DMC leading to EOC Date	
GPR Review Date	Sat Dec 29 00:00:00 UTC 2018
Program on Scorecard?	Yes

REFERENCE INFORMATION

Previous Dashboard Update (date): Tue May 08 04:53:49 UTC 2018	Pediatric Plan (PSP or PIP): PSP—waiver granted
Registration Enabling Studies w/ Endpoints: KN001 (ORR), KN002 (PFS, OS), KN006 (PFS, OS)	Target Patient Population: 1L Patients with metastatic melanoma
Proposed Dataset to Support Next Registration (Including Relevant Interim Analyses): Final analysis	Special Designation: ODD Application: Nov 20 2012 BTD Application: Jan 17 2013
Device/Drug Combo: Yes	JV Development Partner: No
Rap/CoRap/Ref Mem State: Italy/Germany	

MAJOR MARKETS INFORMATION	US/FDA	EU/EMA	Japan/PMDA	Canada/HC	India/CDSCO
Pathway	Standard	CP	TBD	NDS	National
Next Agency Meeting	N/A	TC 17-Jun- 2016	TBD	TBD	N/A
ACM/SAG Meeting	N/A	N/A	N/A	N/A	N/A
Next Filing	P054 (Adjuvant)	26-July-2018	May 2018	Mar 2018	TBD
Approval *	Feb 2019	27-Jan-2019	May 2019	Sep 2018	TBD
CDx/Device File	N/A	CE Mark 28-Dec	N/A	TBD+	TBD
PMC	N/A		N/A	N/A	TBD
Link to GIRS					

Regulatory Risk Descriptions/ Notes

P054 (Adjuvant mel) IA approved. LPLV Oct 2017.
P252 (pembro/epacadostat) Storyboard approved and writing in progress for CSR and CTD. T Filing Incyte NDA Mar 2018 (Merck sBLA May 2018) in US. For EU ,Incyte to file MAA Apr 2018 and Merck will file Type 2 at their Day 150s.
Incyte received FDA feedback that they will file with 9 mo stability data and supplement the 3 mo during 1st month after submission.
PMDA: Prelim meeting with Agency RE: fixed dose. Can proceeed with PK based argument for mel. T: Dec 2017

CMC

FMC Drug Substance Shelf Life (SL) extension to 36 months – CMC released to non-EU CES countries
FMC/CAR SL extension to 24 months – CMC released to AU/NZ, Canada (PMC)
CTA submissions: PN270, PN412, PN581, PN559, PN091, PN522, PN394

MOW

Submitted (CMC): 3 OMAs (Paraguay, Uruguay, Tunisia); 3 RTQs (Russia, Saudi Arabia, Argentina) and 1 Variation (Egypt)
Approvals (CMC): 2 OMAs (Russia, Egypt); 2 Variations BIB/CAR (Philippines, Qatar)

Regulatory Pipeline-Portal View

Mobile View

ADD Regulatory: Visuals

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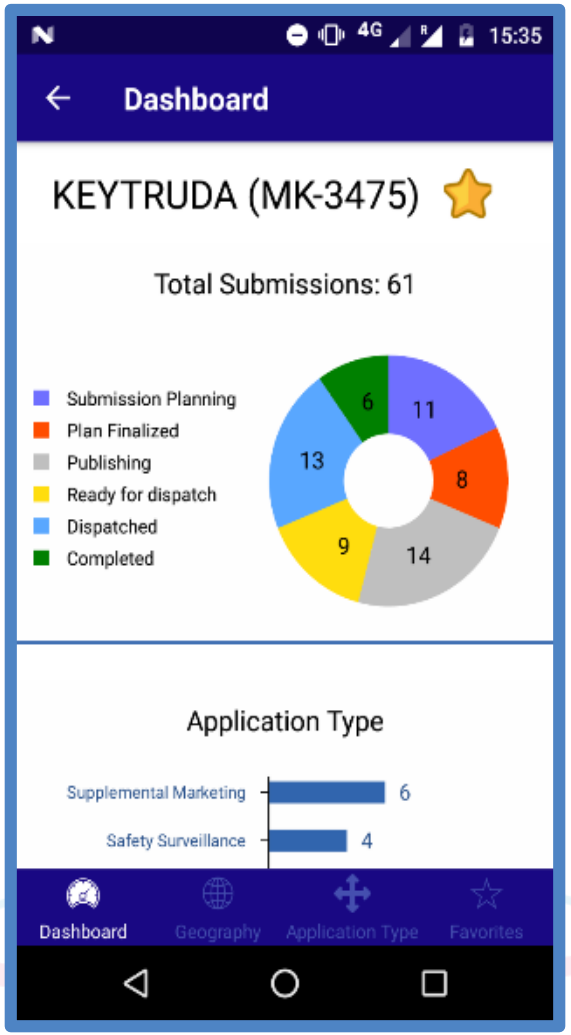
Submission Tracking oversight

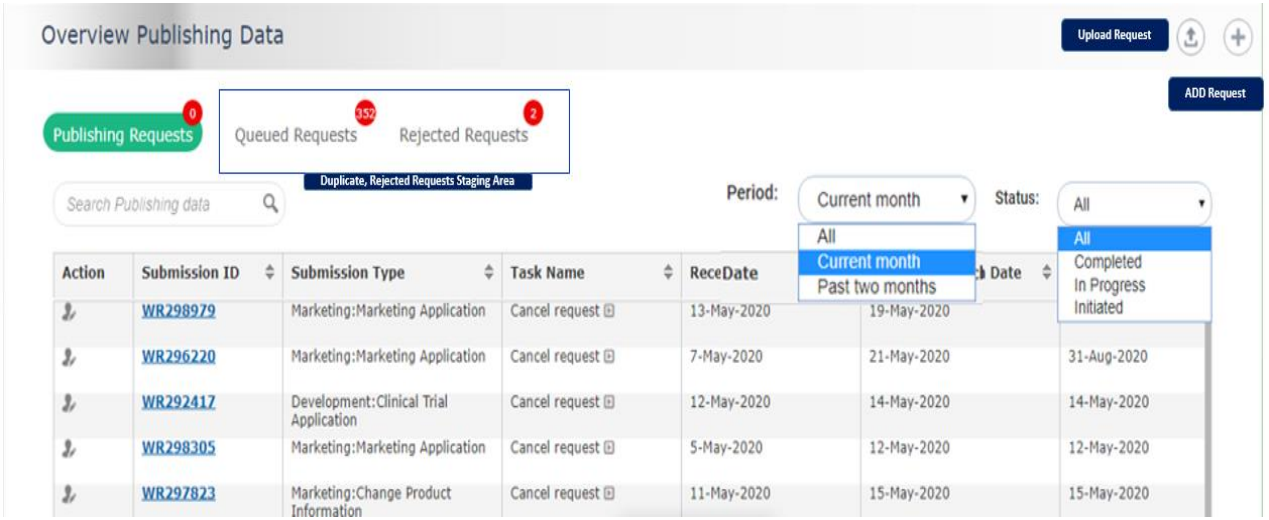


Submission Tracker-Mobile View

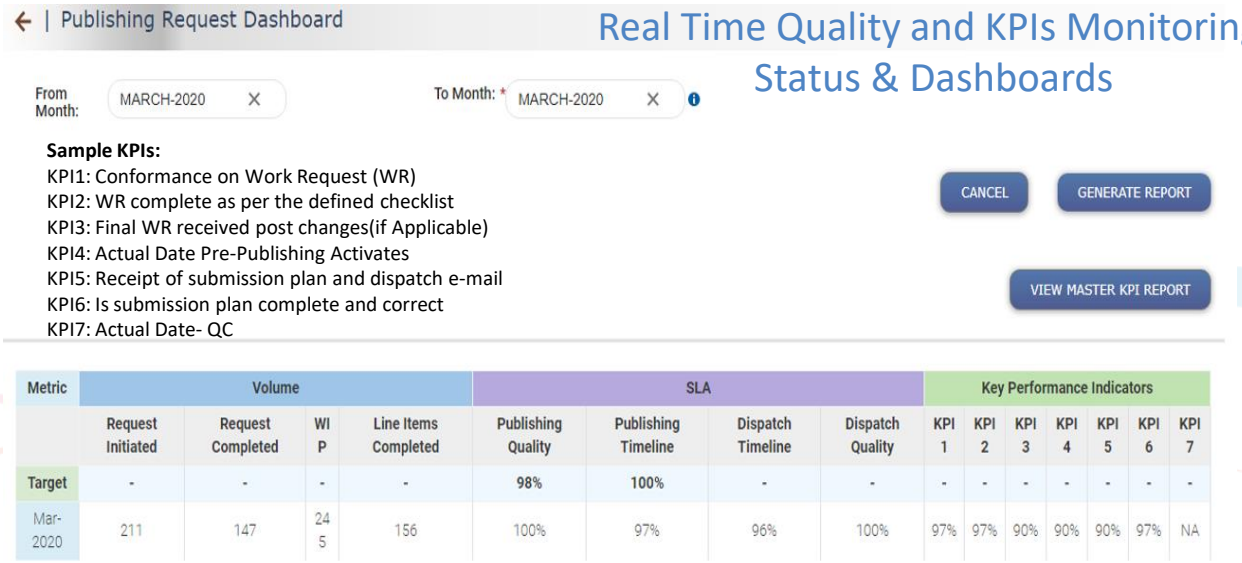
Regulatory Reporting oversight

Regulatory Pipeline-Portal View

Publishing Request Management



Real Time Quality and KPIs Monitoring Status & Dashboards



Metric	Volume				SLA				Key Performance Indicators						
	Request Initiated	Request Completed	WIP	Line Items Completed	Publishing Quality	Publishing Timeline	Dispatch Timeline	Dispatch Quality	KPI 1	KPI 2	KPI 3	KPI 4	KPI 5	KPI 6	KPI 7
Target	-	-	-	-	98%	100%	-	-	-	-	-	-	-	-	-
Mar-2020	211	147	245	156	100%	97%	96%	100%	97%	97%	90%	90%	90%	97%	NA