Transforming Regulatory Affairs through Technology - End to End Tech Platform Approach

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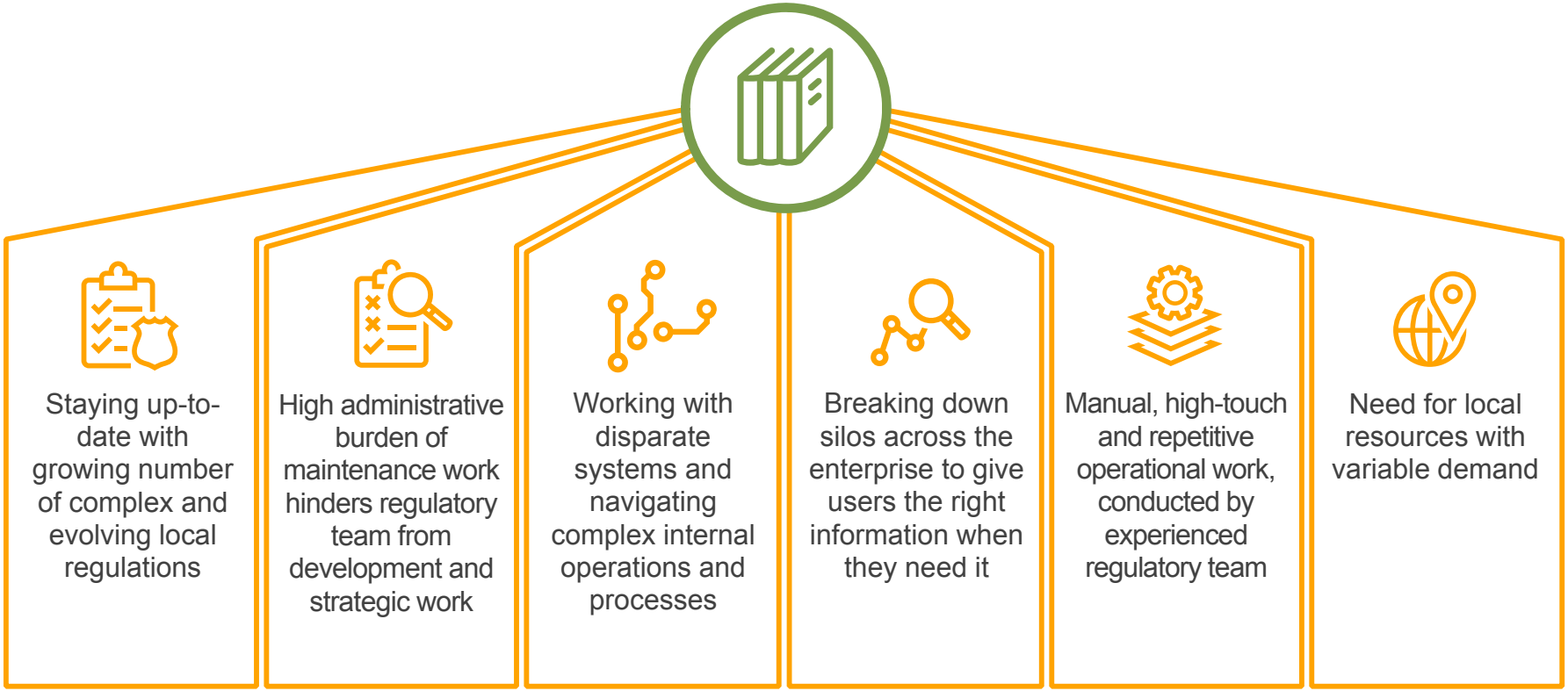
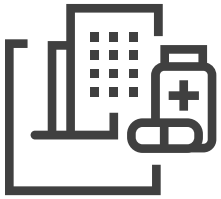
Regulatory Affairs Challenges and Costs

Regulatory Affairs: Key Challenges



Regulatory Operational Burden – What We Are Seeing*

		Regulatory FTEs	Cost (US$)
Mega Multinationals		1296 - 1769	$150m+
Large Multinationals		975 - 1475	$100m+
Medium Multinationals		565 - 1065	$50m+

*Estimates based on internal assessments conducted for pharmaceutical companies and extrapolation

Maintenance Activity and Cost

Maintenance Process

- Labelling changes
  - **SmPCs/PILs/Cartons etc**
- CMC variations
- Safety submissions
  - **PSURs/PBRERs etc**
- Renewal submissions
  - **Annual/5 yearly etc**
- Indication extensions
- Extension submissions
  - **additional countries**
- Submission publishing

Effort

15,000 → 30,000
Individual registrations

7,500 → >15,000
post marketing activities per year

Cost

50 → >60%
of total FTE time spent on maintenance activities

$18m → >$170m
of total FTE time spent on maintenance activities

Optimising Workflows and Automation

Automation Is Central to Efficiency Gains

Foundational Automation

Workflow automation

Mobile user tracking

Enhanced outcome dashboard

Intelligent Automation

AI/NLP

AI owned algorithms

API connectivity

Extreme Automation

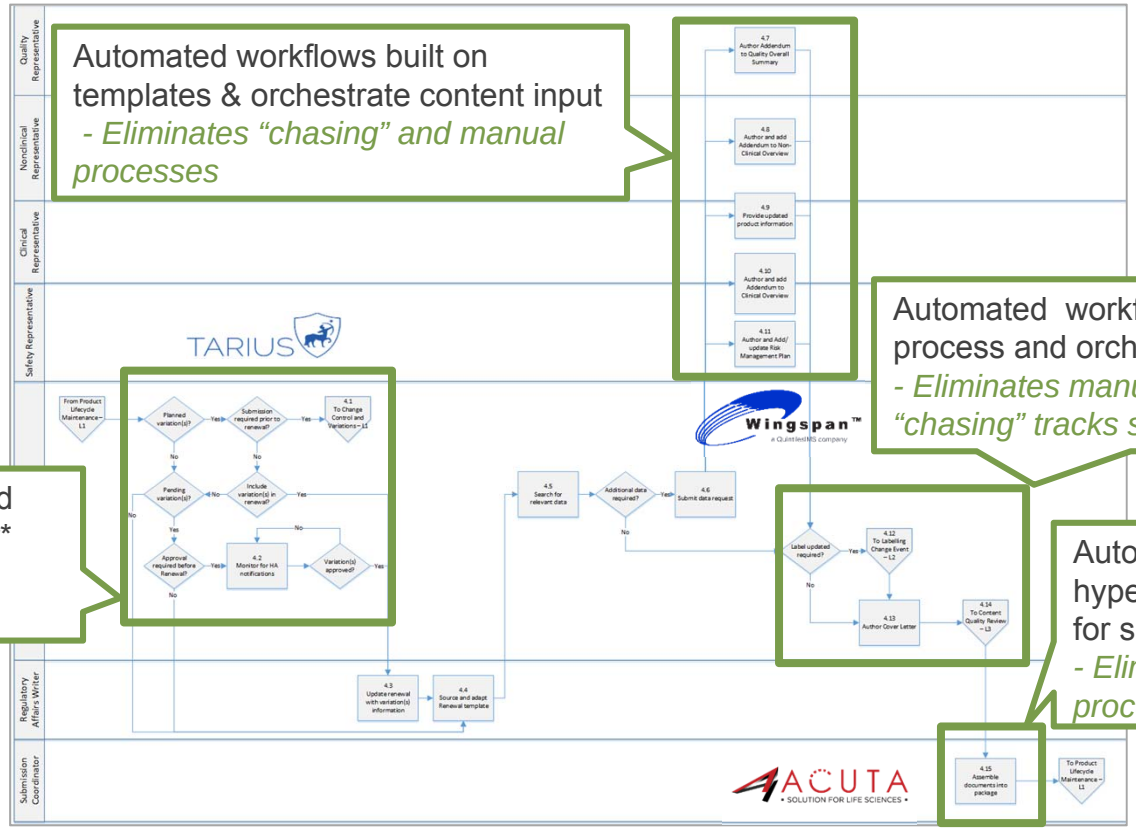
AI/predictive and cognitive reasoning

2nd Gen Blockchain trusted data ecosystem

Robotic process automation

Key Workflow Automation

Example: Renewals



Automated workflows built on templates & orchestrate content input
- Eliminates "chasing" and manual processes

Automated workflows manage labeling process and orchestrate sign off
- Eliminates manual processes, "chasing" tracks sign-offs

Renewal requirements and locations "pushed" to user*
- Eliminates manual "research" phase

Automated workflows, hyperlinking and publishing for submission
- Eliminates manual processes, time and errors

Improving Regulatory Workflows

Manual work transformed to be more efficient and of higher quality

Workflow	Technology Platform Features
General Document Authoring / Review Workflow	GRA workspace; Collaborative document authoring / review/ approval workflow; mobile alerts; planning & tracking; integration with Reg Intel / ECM
Labelling Review	GRA workspace; Labelling change workflow: Collaborative authoring / review / approval workflow, NLP/AI for labelling text generation & translation; mobile alerts; planning & tracking; integration with Reg Intel / ECM
Regulatory Operations	GRA workspace; Submission planning workflow; collaborative review / approval; mobile alerts; planning & tracking; integration with Reg Intel / ECM
CMC Review	GRA workspace; CMC review workflow; collaborative review / approval; mobile alerts; planning & tracking; integration with Reg Intel / ECM
Ad Promo Review	GRA workspace; Ad Promo review workflow; NLP comparison between advertisements and approved label; collaborative review / approval; mobile alerts; planning & tracking; integration with Reg Intel / ECM

Regulatory Intelligence

Regulatory Intelligence – Platform Needs

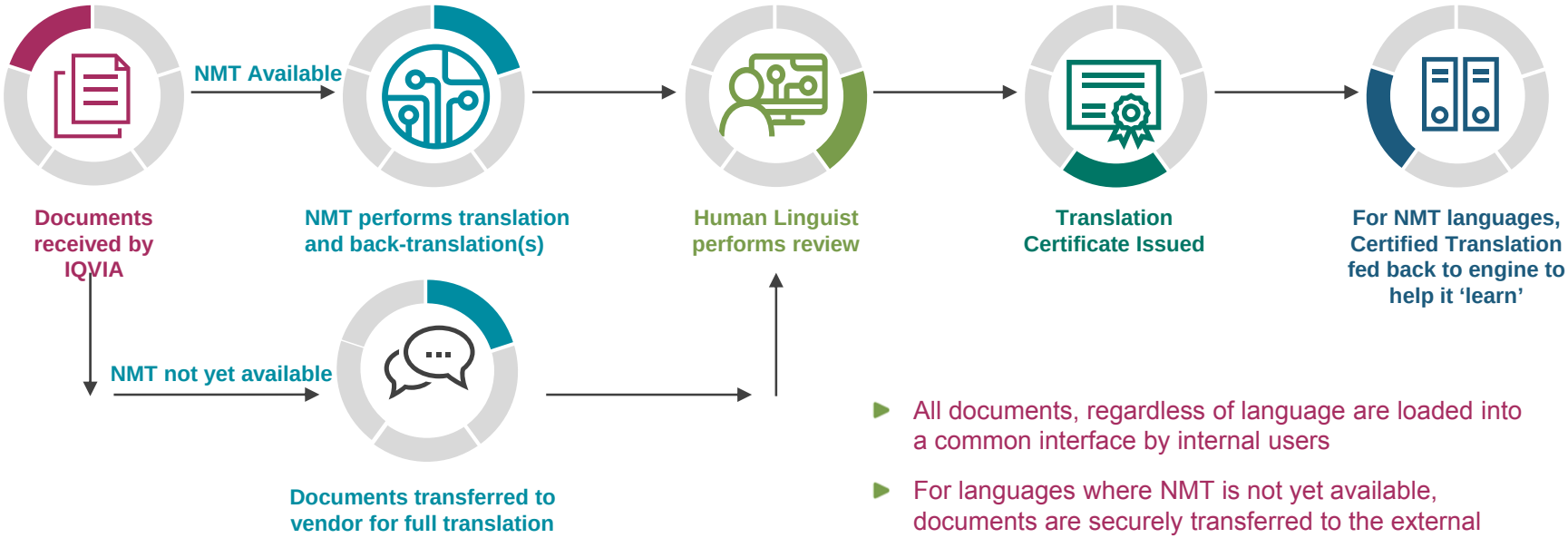
Ensure that global regulatory requirements are easily accessible and understandable

Coverage	Drugs and Biologics	Devices & IVDs
Geographical coverage	89 countries plus relevant regions and organizations	89 countries plus relevant regions and organizations
Reference documents	~175,000 for Drugs	~65,000 for Medical Devices
Translations	Repository of Machine Translated documents	Repository of Machine Translated documents
Cross-Country Tables	Clinical Trials / Fees / GMP & GDP / Marketing Authorisation / Safety	Classification / Fees / Import/export / IVDs / Marketing Clearance / Safety
Expert Summaries	~1,700 Expert Summaries	~1,500 Expert Summaries
SAC Tracker	FDA Advisory Committees documents and voting history of members. Background Analyses, Briefing Summaries, Result Wires and FDA Decision Report	
Unique Features		

Neural Machine Translations

Automating Translation to enhance efficiency

Neutral Machine Translation (NMT) - Human linguist performs review or full translation dependent on language



- All documents, regardless of language are loaded into a common interface by internal users
- For languages where NMT is not yet available, documents are securely transferred to the external vendor for full translation

NMT Translation Engine Fast Facts

Time to create initial machine translation of a ~100 page protocol

<2 Minutes

90%

Initial machine accuracy for Spanish for Spain & General Latin America

From Weeks to Days

Potential reduction in translation turnaround time of up to 50% using NMT

Continuous machine learning allows NMT translated documents to incorporate preferred in-country speech patterns and required voice (informal/formal tone)

Multiple file formats accepted including PDF,.DOCX and scans

Intuitive interface improves **transparency** of document collection & flow for teams and vendors

25
Planned Languages for NMT

Q1 2019
- 14 in production

Q4 2019
- Additional 11

NMT maintains document formatting. Delivers a translated document with the **same rendering as the submitted file**

Regulatory Technology Platform

Reg Tech Platform Needs

Tech platform based on functional area needs

- Simple and easy to use **interface**
- Built-in **work-flows** and **validations** based on the functional area user requirements
- Role based **security** & **access** to manage users
- **Cloud based** solution with access from anywhere
- Support for global **Publishing**
- **Common data** for products, organizations, etc. for Publishing, Agency Interactions & Registrations
- **Integrated Viewing** of eCTD and non-eCTD electronic submissions with controlled access and workflow

Desired Outcome

Developing new solutions to improve efficiencies across Regulatory Services

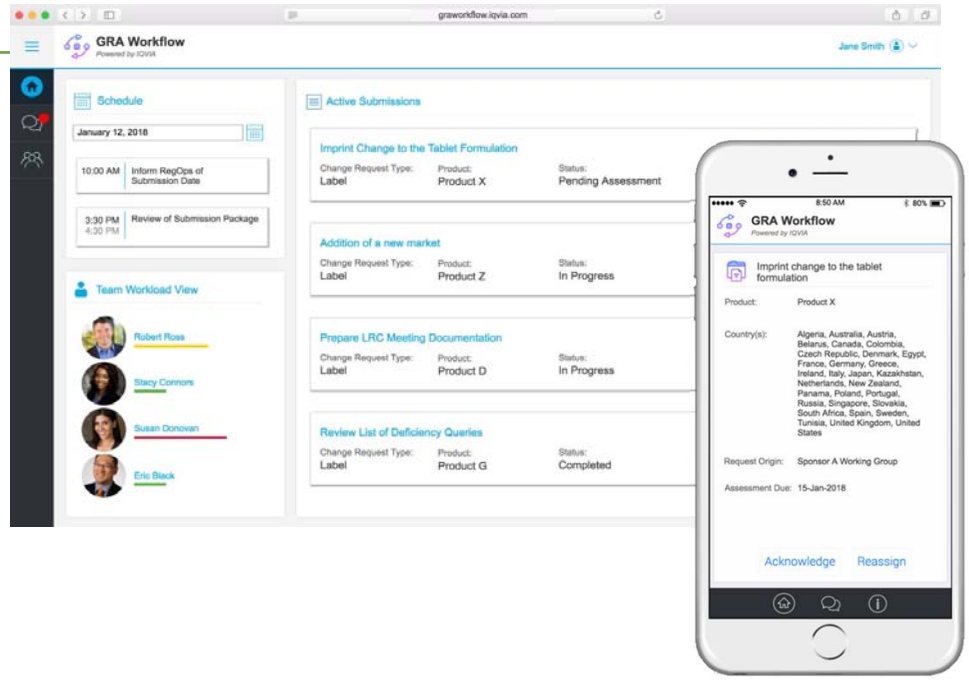
Simplify Regulatory Affairs

Streamline daily work:

- Robust planning & tracking, including mobile tools, to provide global transparency of required work
- Integrate content management, regulatory intelligence, and publishing tools into a single robust user interface for ease of use
- Automate routine content creation
- Push vs Pull process flow

Benefits:

- Reduces manual workload and repurposes experienced staff to more high value strategic activities: right person, right task
- Eliminate up to 80% of routine tasks through automation
- Do more with fewer people and less effort
- Improve quality with fewer touchpoints



IQVIA RIM Plus - at a glance

Regulatory Intelligence

- Easily accessible global regulatory requirements for 89 countries
- Regulatory Documents: 175K for Drugs; 65K for Devices
- Over 3200 expert summaries: Fees/Authorizations/Safety Info
- FDA Advisory Committee documents/decision reports

Correspondence & Commitments

- Real-time access to relevant health authority correspondence and commitments
- Access to regulatory source documents and associated commitments with status
- Increased speed and accuracy of commitment responses

eSubmission Viewer

- Provide real-time access to all regulatory submissions for all individuals involved in the process
- Share submission/documents securely with external partners

Product Registration & Tracking

Regulatory Content Management

- Streamlined for creating compliant, submission-ready, content
- Adherence to eCTD granularity and PDF requirements
- Synchronized with Master Data Management
- Automated metadata with minimal data entry needs

Submission Planning

- Provides a link between agency commitments and regulatory submissions
- Resource and time management
- Ensure faster response time
- Information at your fingertips
- Control over the process and workflow

Publishing & Validation

- eCTD & RPS format submissions
- Non-eCTD electronic submissions
- Rest of the world PDF based submissions
- Validation
- Life Cycle management
- Control over the process and maintain data consistency

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