

ThermoFisher
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ATLASSM

Alternative Translation & Label Approval System

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Challenges with Label Text Approvals



Label text approval management is handled using notebooks or Excel spreadsheets



Need to constantly send reminders to CROs or affiliates



Label text approvals delay every other aspect of a study



Internal phrase libraries are difficult to navigate



Clinical supply chain roles taking on additional workload, which includes label text management



Job setup could take 4 to 6 hours per job



Managing the back and forth with CROs or affiliates can be arduous and time consuming



No metrics to hold country managers or affiliates accountable for late approvals

ATLASSM—Alternative Translation and Label Approval System

The only system available to address the full spectrum of label development, from text translation and approval through label manufacturing

- Proprietary web based system
- Organizes the entire clinical labelling project
- Online ordering tool
- Manages translations and text documents
- Tracks all document changes and places
- Reduces timelines on each phase of the label text

The screenshot displays the ATLAS web application interface. The top navigation bar includes 'Home', 'Orders', 'Projects', 'Tasks', 'Affiliates & Users', 'Repository', and 'Phrase Library'. The main content area is divided into three sections: 'ACTIVE ORDERS', 'ACTIVE PROJECTS', and 'ACTIVE TASKS', each with a pie chart and a list of items. The 'ACTIVE ORDERS' section shows a pie chart with 2 Pending, 1 Submitted, 1 Rejected, and 3 Accepted orders. The 'ACTIVE PROJECTS' section shows a pie chart with 22 Pending, 11 Active, and 1 On-Hold projects. The 'ACTIVE TASKS' section shows a pie chart with 31 Pending, 5 In-Process, 5 Completed, and 5 Cancelled tasks. The right side of the interface features an 'ALERTS' section with three alerts for 'Test Clintra', 'Test 23', and 'Test Project', each indicating an overdue status. Below these sections is a detailed view of 'Phrases By Category'. This view includes a search bar, a table of phrases, and a 'Generate Document' button. The table has columns for 'Set', 'Phrase', 'Language', and 'Font'. The 'Set' column is currently selected, and the table is displaying 15 rows of phrases. The right side of this view includes a 'Sample output' section with a table of translation sets and a 'Translate selected phrases to:' section with a list of languages to translate to.

Benefits to Sponsors

- Releases clinical supply chain team from time consuming label text routing and approval tracking
- Reduces overall label generation cycle time
- Reduces excessive communication with CROs and affiliates
- Condenses overall label text approval timelines and regulatory review
- Provides KPM reporting on issues and delinquent approvals
- Intuitive to use—subjects single data download, single tracking system
- Secure system—data protected
- Accurate and efficient—automated and validated systems
- Access to job information 24/7

1

ATLAS translation services is a unique solution in this industry. Most companies offer translations, regulatory service or a system to manage the process.

2

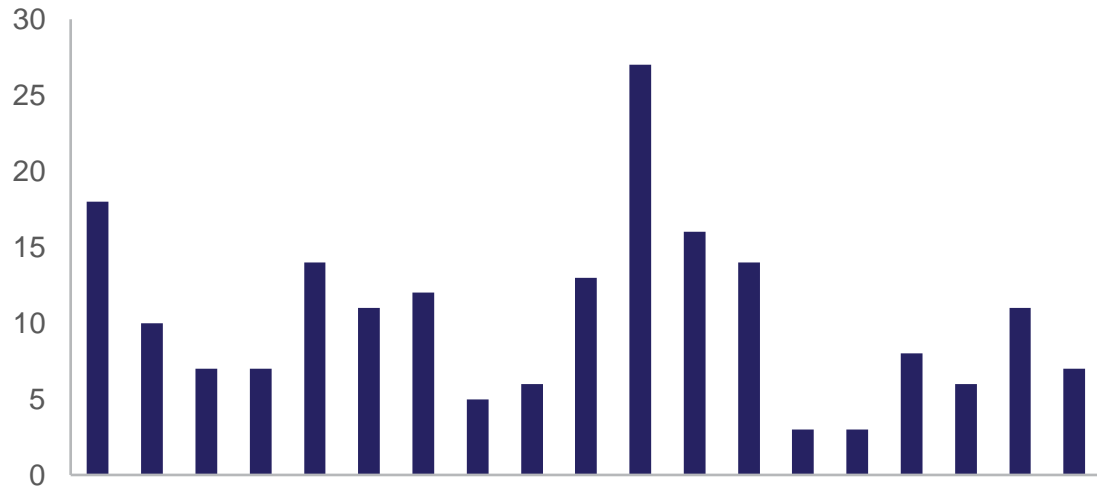
ATLAS is not a standalone system and it is not a plug in system. It is part of a strategic partnership between the sponsor and Fisher Clinical Services.

3

No other company combines the system and service to reduce costs, timelines and resource constraints—getting drugs to patients faster.

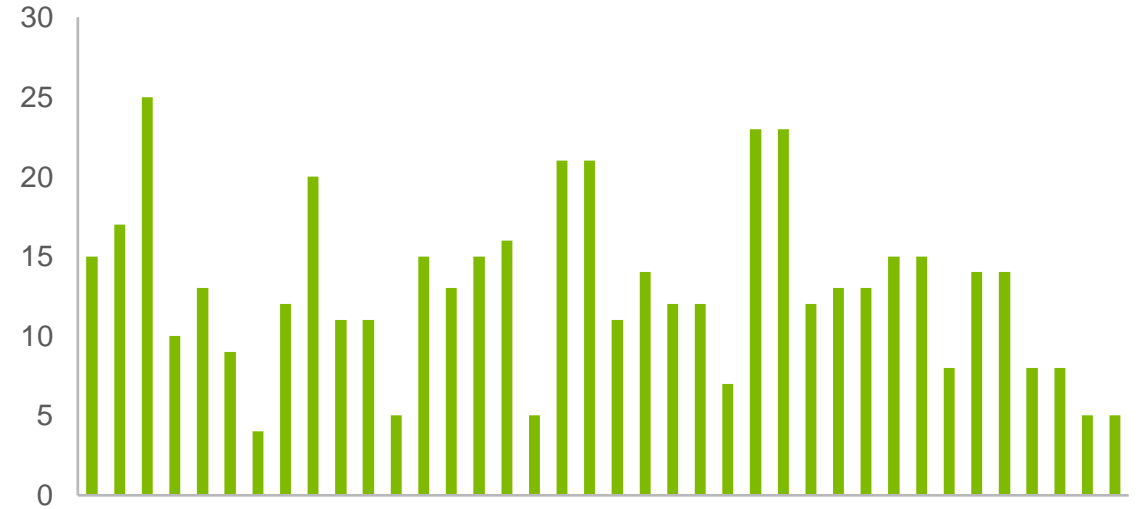
Case Studies Highlight Reduced Timelines

■ # Days



- Large pharma client
- Previous process tracked at ~115–125 days
- Order placement, proofs created, proofs approved, QA approved
- All work runs through ATLAS regardless of packaging provider

■ # Days



- Large pharma client
- Previous tracked at ~160 days
- Order placement, proofs approved
- All work runs through ATLAS irrespective of packaging provider

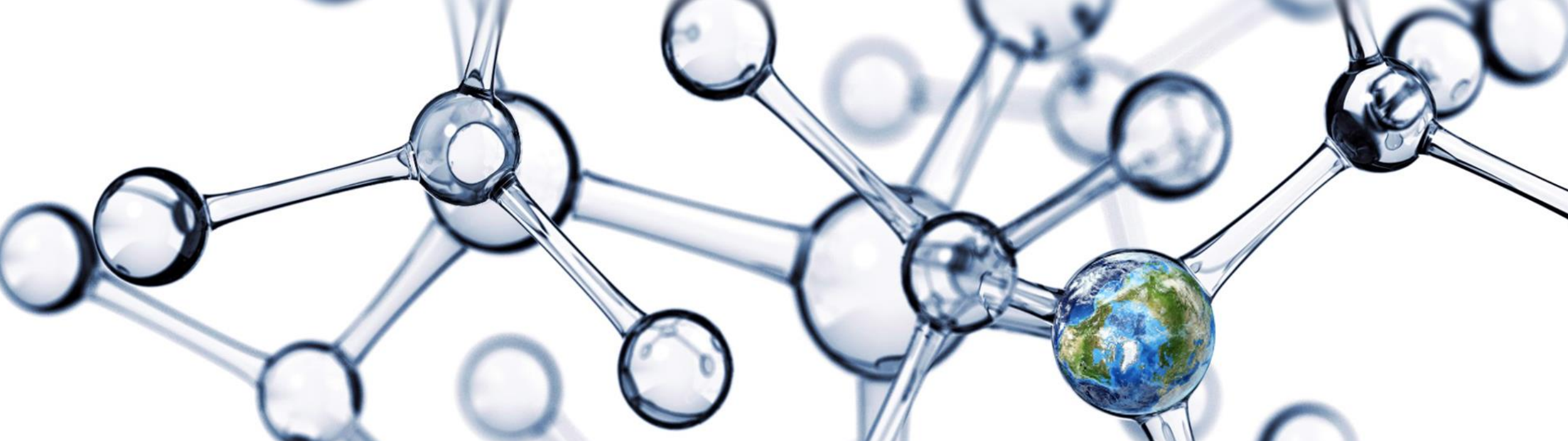
FYI: Client on left is Eli Lilly and client on right is Regeneron

Database of certified phrases and regulatory content for all studies developed in ATLAS

- Eliminates need to repeat translation activities
- Eliminates need to constantly recertify country regulatory requirements
- Allows flexibility in cases of country's adding or dropping
- Allows flexibility to select new phrases at a later stage

Proven record of maximizing efficiencies

- Successful cycle time reductions of 50% or more—months into days/weeks
- Reduced cost of repeat activities—translations/regulatory
- Reduced error rate as opposed to repeated/manual process
- Less need for internal resources to manage time consuming process



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