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SHARED SERVICE MODEL IN LABELING: DRIVING EFFICIENCIES

BETTER OUTCOMES DELIVERED WITH ATOM

SHARED SERVICE MODEL IN LABELING: DRIVING EFFICIENCIES

CONTENTS

INTRODUCTION

Product Labeling in the biopharmaceutical and medical devices industry is a complex process that involves dealing with several dynamics, viz. a geographically dispersed manufacturing infrastructure, multiple products in multiple markets, different formulations and doses, involvement of several functional stakeholders, variations in local product labels and a constantly changing regulatory environment.

Errors, omissions, and mistakes in product labels can prove to be extremely costly. Industry experts estimate that 35% to 40% of pharmaceutical product recalls are due to errors in labeling and packaging.[1] The financial impact of such errors can be significant not only due to revenue lost from unsaleable products but also due to costs of litigation, fines, and drops in stock prices. In 2011 alone, during a 6-month period, the FDA recalled 455 products, 51% of which were attributed to errors in labeling and 13% to faulty packaging.[1]

It is no surprise, therefore, that companies place a lot of emphasis on their labeling operations.

LABELING PROCESS

For a product in the market, there is an ever-increasing volume of information and data about its safety and efficacy. Regulations require the marketing authorization holder (MAH) to promptly and frequently update the Company Core Data Sheet (CCDS) to reflect any new safety signals, efficacy data, warnings, etc. Further, these updates in the CCDS need to reflect accurately in the product's label within pre-defined timelines so as to meet the global and local compliance requirements.
An update in the CCDS triggers the need to update the Local Labeling Document. For companies with multiple products approved in multiple countries, the management of Structured Product Labeling (SPL) both global and local is a colossal task. It includes maintaining and updating the CCDS for all products, evaluating the need for changes to the CCDS and local labels, comparing local labels with the CCDS to ensure consistency, and documenting the rationale for making/not making changes. It also involves ensuring that the frequency of changes in the CCDS for new label submissions is also managed as per the guidelines from the health authorities.

LABELING SERVICES INCLUDE

- Creation of/updates to CCDS and CCSI (Company Core Safety Information) as per updated information related to product safety; clinical outcomes; drug metabolism and pharmacokinetics (DMPK); preclinical research; and chemistry, manufacturing, and controls (CMC)
- Development of clinical overviews to support label updates
- Comparison and alignment of local labels with CCDS
- Label updates and translation of local product/patient labels based on updated CCDS
- Proofreading of CCDS and local product/patient labels
- QC and review of CCDS, CCSI, and local labels
- Coordination activities for label management
- Response to all health authority queries based on updated CCDS and local labels
- Dispatch, archival, and documentation

455

PRODUCTS RECALLED BY FDA IN 6 MONTHS IN 2011.

LABELING PROCESS: HOW THEY ARE CURRENTLY MANAGED?

Given the criticality of running an error-proof global labeling process, pharmaceutical companies have developed detailed SOPs for every step in the process and implemented comprehensive monitoring and governance plans.

Despite these stringent measures, meeting the timelines while ensuring accuracy of information for health authority submissions poses a challenge because of the involvement of multiple teams and stakeholders from different geographies. In several cases, highly trained resources spend time in relatively simple and mundane logistical activities such as cross-functional co-ordination and project tracking just to ensure adherence to submission deadlines.

With the increasing challenges of cost pressure, headcount freezes, frequently changing regulatory requirements, and, "glocalization" of labels, bio/pharmaceutical companies are adopting a variety of operating models to remain competitive and meet their tactical requirements for individual processes.

Most pharmaceutical and medical devices companies have developed workable solutions by adopting either a "de-centralized" or a "regionally centralized" model.

DECENTRALIZED MODEL

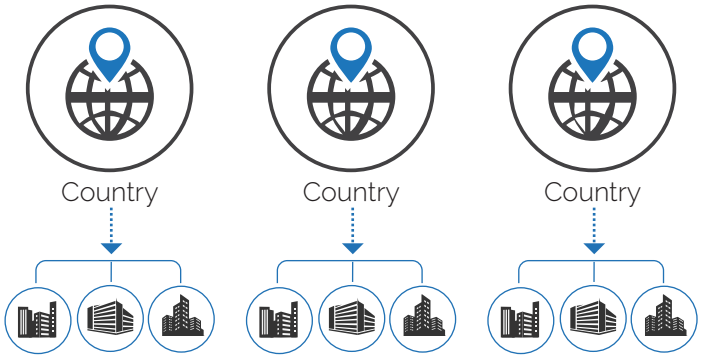
The de-centralized model has been evolutionary rather than revolutionary. As business expanded organically, companies have established local operations for product labeling wherein each country or region manages the process end-to-end with local resources, infrastructure, and governance. The de-centralized model has certain inherent advantages such as complete ownership and control in the hands of the local operational leadership, local market understanding, and speed of decision making.

However, as companies and markets have become more globally integrated, the de-centralized model has encountered challenges such as lack of standardization of processes, inconsistencies in data,

51%

PRODUCT RECALLS BY FDA ATTRIBUTED TO ERRORS IN LABELING AND 13% TO FAULTY PACKAGING.

Decentralized Model



A GLOBAL SHARED SERVICE MODEL (SSM) STRIKES THE BEST BALANCE BETWEEN LOCAL MARKET RESPONSIVENESS TO THE EXTERNAL ENVIRONMENT AND THE NEED FOR GLOBAL COMPLIANCE, STANDARDIZATION, QUALITY, SPEED AND COST-EFFECTIVENESS.

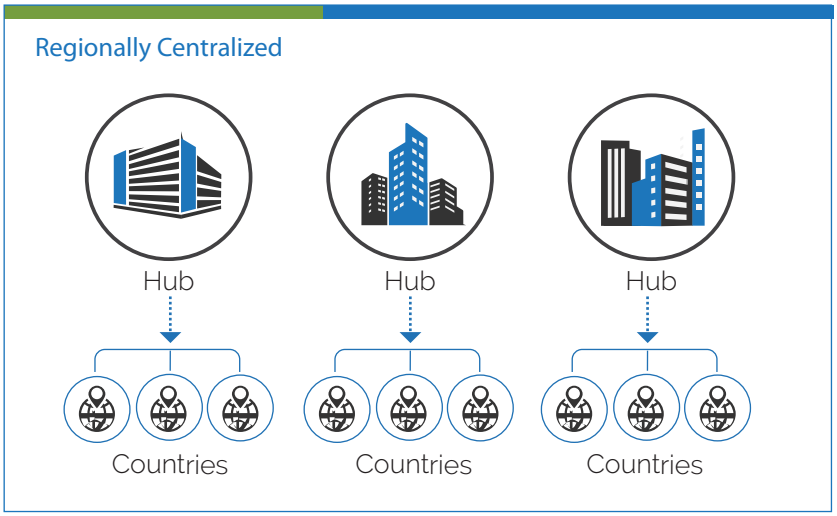
outdated repositories of knowledge, and inadequate availability of expertise. More importantly, the model suffers from delays in implementation of global CCDS changes in the local labels and risks of non-compliance to global regulatory requirements. Further, there is an inherent need to replicate the operation in each local office in this model, resulting in cost-inefficiencies.

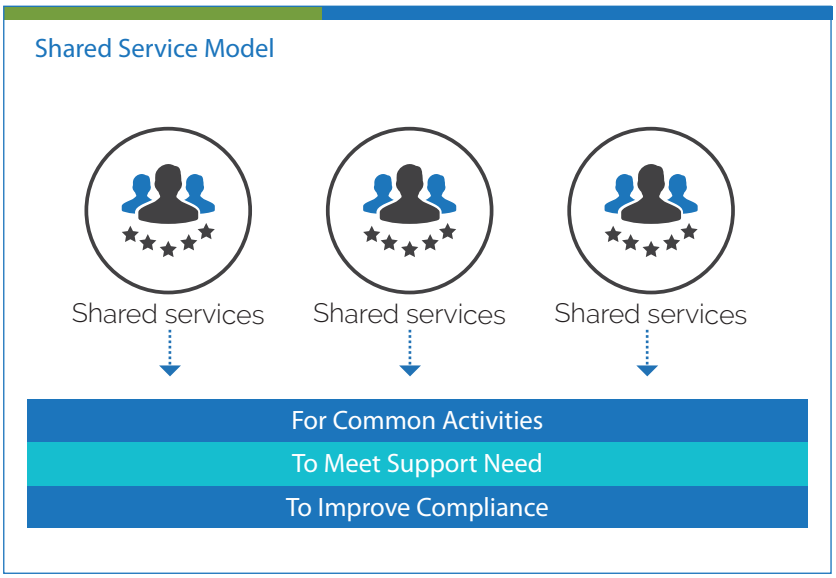
REGIONALLY CENTRALIZED MODEL

Several companies have tried to address the challenges endemic to the de-centralized model by evolving a hub and spoke model with a quasi-federal structure in which regional hubs manage aggregated work processes for groups of countries, while the individual country offices are responsible for more tactical activities and to feedback local regulatory nuances to the hub.

The regionally centralized model does address some of the challenges with the decentralized model, but has some of its own limitations such as lack of standardization across hubs, imbalance of resources and expertise, variable degrees of alignment to global guidelines and standards, replication of operations, and sub-optimal cost efficiency.

Although the regionally centralized model is a marked improvement from the de-centralized model from the perspective of global compliance, some of its limitations point to the need for a re-think on the best way to manage global and local labeling operations.





SHARED SERVICES MODEL

From our experience of working with some of the world's largest pharmaceutical companies in the area of product labeling, we have found that a Global Shared Service Model (SSM) strikes the best balance between local market responsiveness to the external environment and the need for global compliance, standardization, quality, speed, and cost-effectiveness.

In this model, the local market understanding and last mile implementation continues to lie with the local centers of the organization in each country, while all aspects of labeling operations are de-coupled and consolidated into a single global shared service. The table below provides an overview of the set of activities that are typically consolidated centrally in the SSM and the types of activities that continue to be the responsibility of local operating companies.

Shared service model vs. localized model.

Shared Service Location	Localized
• Creation of/updates to CCDS/CCSI and local labels (product/ patient)	• Country-specific customization of labels and associated translation and back translation
• Label comparisons and assessment of medical deviations	• Coordination of translation services and tracking
• Preparation of justification documents (clinical overview [CO], tailored CO, reference support)	• Preparation of responses to queries from the local health authority based on updated CCDS and local labels
• Data consistency check, quality review, and proof-reading of CCDS and local labels	• Dispatch, archival, and documentation
• SPL-PLR conversion services	
• Compliance tracking and reporting	
• Audit support	
• Administrative/document management support	
• Artwork and labeling implementation	

The global shared service ensures compliance, standardization of processes and timely alignment of the LPD to CCDS. Further, it pools talent and expertise, which enables more flexible resource allocation and drives greater cost-effectiveness through consolidation. Since the activities at the local level are primarily strategic and related to addressing last-mile needs, the SSM requires only a thin layer of expertise in each country. In addition, since all operations are consolidated, it would be far easier for global regulatory affairs to ensure compliance, track errors, and drive quality improvement.

One of the goals of the SSM is to continuously drive process improvement by setting higher benchmarks for cycle times, costs, and quality. The centralization of operations ensures that any process improvement yields benefits to all country operations simultaneously.

There is an ever-growing use of technology tools to drive process improvement. Deploying tools that can manage the labeling workflow; drive collaboration; compare and contrast documents; proofread, edit, and perform QC on documents; and help in repurposing content written once to be deployed several times are some of the ways to drive both compliance and process efficiency in labeling.

The SSM reduces the time and costs for implementation of such tools and ensures that all labels worldwide are being developed using the most current set of platforms and software. As the company encounters changes in global and local regulatory requirements, expands its operations into newer product areas and geographies, and enters into mergers and/or acquisitions, the SSM helps ensure that label management remains consistent and compliant.

STRATEGIC TRANSFORMATION

Our experience has been that the SSM in labeling can open up avenues to integrate backward and forward so as to straddle the continuum of work-streams from safety case processing to packaging artwork management. By doing so, companies can seek to transform and seamlessly integrate the end-to-end process that begins with signal identification and ends with a modified product package and label on the shelf.

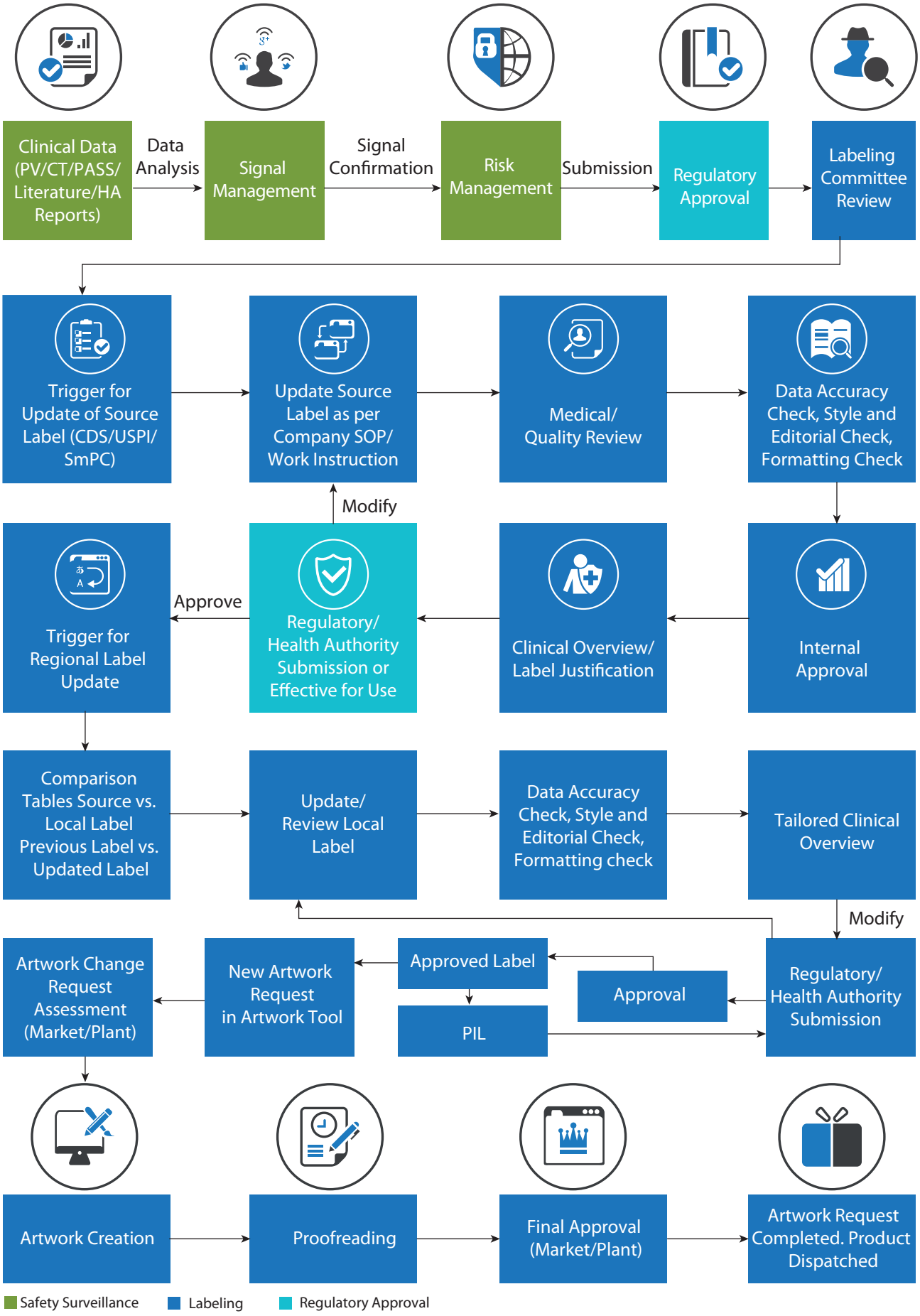
The continuum of such an integration is shown below. Our experience has been that while several companies have consolidated individual elements of this continuum, very few have moved down the path of integrating them all together into one single SSM. The integration may not happen sequentially, but we are already witnessing some progress in some of our client engagements.

OUTSOURCING OF LABELING OPERATIONS

Pharmaceutical companies are now increasingly looking at outsourcing some or large parts of the labeling processes. The degree to which labeling work streams are outsourced depends essentially on the execution

THE CENTRALIZATION OF OPERATIONS ENSURES THAT ANY PROCESS IMPROVEMENT YIELDS BENEFITS TO ALL COUNTRY OPERATIONS SIMULTANEOUSLY.

Integrated Labeling Management Process Flow

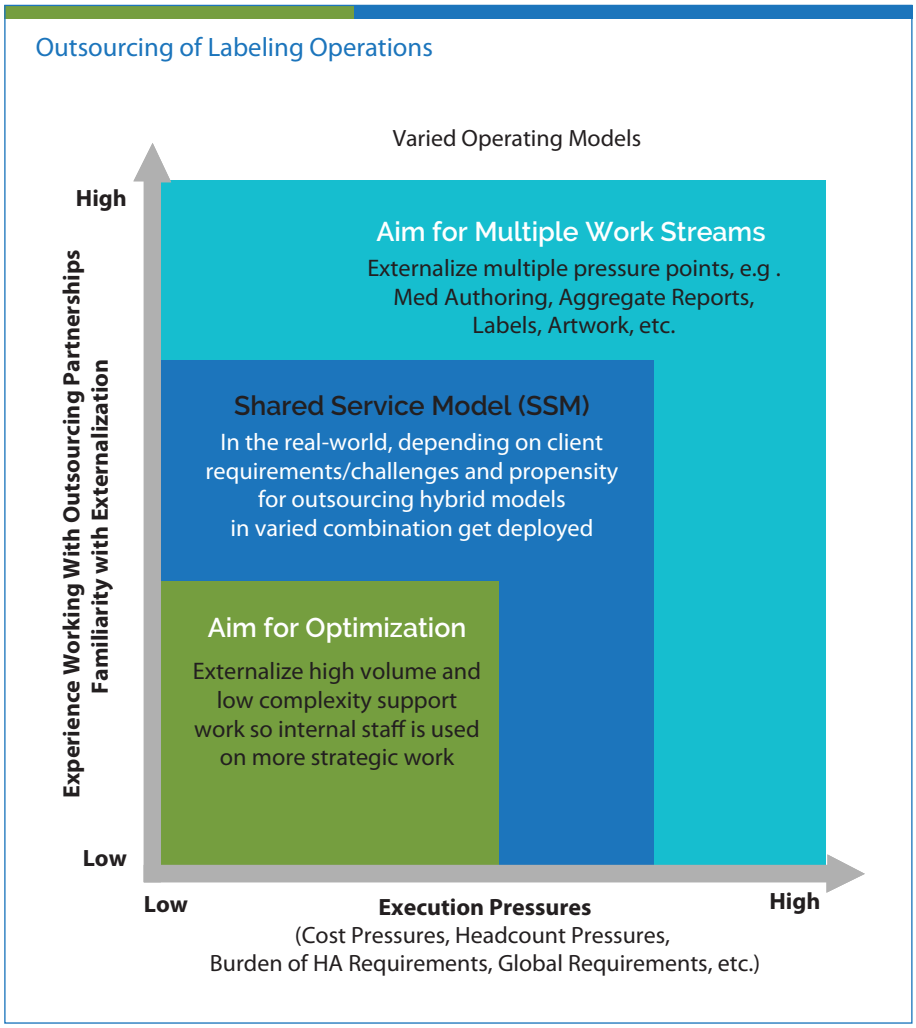


pressures that a pharmaceutical company faces within and also on its familiarity with externalization or outsourcing.

For example, if execution pressure and familiarity with externalization is low, the objective is "to optimize" by externalizing high volume and low complexity support work so that key resources are channelized

for more strategic work. Work streams that tend to get easily outsourced include activities such as coordination, translation, review of CCDS, etc. However, if the sponsor is reasonably familiar with externalization, the aim is to simultaneously outsource not only routine activities but also "multiple work streams," sometimes in an end-to-end partnership model.

In the real world, hybrid models in this continuum are deployed depending on the sponsor's requirements/challenges and propensity to outsource. Sponsors who have adopted hybrid models meet routine expectations such as improvement in processes and timelines for updating/creating CDS and local labels, streamlining work streams, and accessing some of the innovative technological tools.



SUMMARY

We believe that global biopharmaceuticals will reap significant benefits by exploring alternate approaches to the existing operating models in labeling.

By adopting the SSM, colocation of local expertise and consolidation of similar activities would provide benefits such as better compliance, right balance between the local expertise and consolidated team, better responsiveness, consistency, visibility on utilization of resources, overall process governance, and cost savings.

With the presence of multiple products in multiple countries, and regulatory requirements necessitating compliance with local health authorities for each product, there is a need for an SSM model that would outweigh the benefits seen in any traditional model.

The SSM will provide these strategic benefits to the sponsors by minimizing operational issues and providing efficiency, access to proprietary technological innovations, and standardization of routine operations.

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