



Visiontracker

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ENVISION PHARMA
GROUP



Case Study

Optimizing Collaboration in Emerging Markets

Common challenges become increasingly difficult to overcome when studies extend into emerging markets. Tracking activities and data trends are essential components to improving studies, both at home and in emerging markets. In this case study, learn how stakeholders implement strategies to achieve successful collaboration when stakeholders and data are in the global market.

- Analyze budget plans and study activities
- Examine activity and data trends
- Maximize investment strategies
- Establish proper budget planning, time frames, and portfolio management

Introduction

In recent years, external activity support and management in the life sciences industry have undergone dramatic changes. Regulatory, financial, legal, risk management, business needs, and customer-relation landscapes have shifted, requiring companies to become more transparent in their global operations. Yet, the demand for local research supporting safe and efficacious product use, local health care economic and reimbursement data are increasing. Reporting of affiliate activities in emerging regions will soon become a standard practice across global organizations because of regulatory and legal pressures. To this point, implementation of simple, common processes that are flexible while maintaining compliance and transparency is needed. This case study will review the implementation of Envision's Visiontracker for global investigator initiated trials (IIT).

Business Landscape

The company profiled in this case study is a global life sciences company. The company is organized as separately managed business units that are led by independent leadership groups responsible for setting strategy, goals, and budgets. Clinical activities are managed independently, including IIT strategies, budgets, and activities. Global IIT reporting is rolled up to the corporate clinical organization for strategic, resource, and compliance review approval and reporting.

Regulatory/Compliance Environment

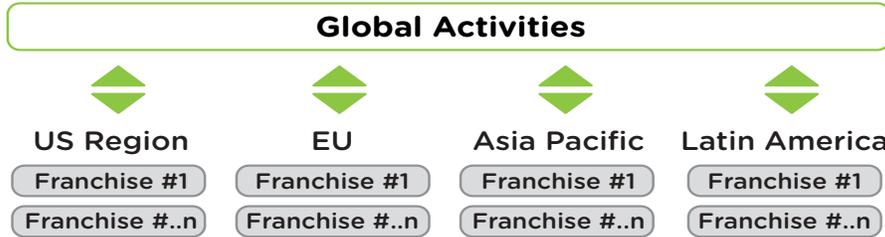
Because of the increased scrutiny of the life sciences industry by global regulatory agencies, internal and external transparency of health care professionals (HCP) interactions has become more important. The Sunshine Act, Foreign Corrupt Practice Act, UK Bribery Act, and other global compliance laws are requiring multinational corporations to manage, maintain, and report on a regular basis all HCP activity and associated payments. To meet this challenge, companies are retooling siloed processes to create common best practice solutions to improve efficiencies, reduce costs, and to require supported HCP activities to be compliant and completed in a timely manner at fair market value.

Business Need

Regional evidence development continues to be a vital business requirement. These data expand on the primary base of evidence developed during the regulatory approval process by developing health care economic, reimbursement, regional demographic, and local phase IV evidence. When well done in a compliant manner, global independently sponsored studies can provide a substantial body of evidence that can be leveraged to support a product's safe and efficacious use. Implementing Visiontracker can reduce affiliated siloed processes to facilitate the effective use of global data development programs.

Strategic Development

Regional strategic activities should be leveraged across the organization. Unfortunately, it is difficult to capture global activities and outcomes without a comprehensive system and common processes. Alignment and development of these processes can be painful, but with increasing global government scrutiny across the industry, it's becoming a necessity. From a strategic standpoint regular reviews of current ongoing activities as well as development of future directions are needed to drive efficiencies, growth, and global alignment.



Implementation

Design and implementation of a system to easily manage external and internal activities can be a daunting task. Due to existing silos and entrenched behaviors, gaining alignment within a large global organization is difficult. Organization of a steering committee charged with the task is needed. This cross-functional, cross-regional, cross-business unit team is responsible, accountable, and needs to be given the authority to make final decisions. The goal of this team is to establish a process and system that is compliant, flexible, easy to manage, reportable, and scalable to meet the needs of the global organization. Because of Visiontracker's configurable architecture, it is the perfect tool to meet these needs.

Step 1: Review existing processes to create a best practice approach

Stakeholder identification is important to accurately review and evaluate current processes used across the organization. A cross-functional team was assembled consisting of members of the clinical organization from each business unit in addition to IT project management. These individuals had direct experience or were responsible for tracking and managing the process for external research. Each member of the team provided details, SOPs, and presented how their process is managed. The team evaluated all processes to create a comprehensive list of best practices that was presented to leadership. This detailed list of agreed-upon best practices was the basis for the final process. In addition to defining the process, it brought together alignment for a comprehensive policy.

Step 2: Policy development

To gain alignment throughout the organization and finalize the process, an overarching policy was developed. The policy statement provided the structure and backdrop to further define the more detailed process steps. This document was also used to educate internal and external stakeholders as to what was expected by the organization as a whole. Items included mission statement, activities supported, types of support provided, roles and responsibilities, identification of the sponsor, and procedure summary.

Global Policy

Provides the overall structure for the process. Used to educate internal and external stakeholders. The policy should include; Mission Statement, activities supported, types of support, roles and responsibilities, identification of the sponsor and process summary.

SOP

Used to define the new internal process and is aligned with corporate operating standards.

Work Instructions: GBU #1

Details of the processing as defined by the business. Able to clearly define steps and actions needed.

Work Instructions: GBU #2

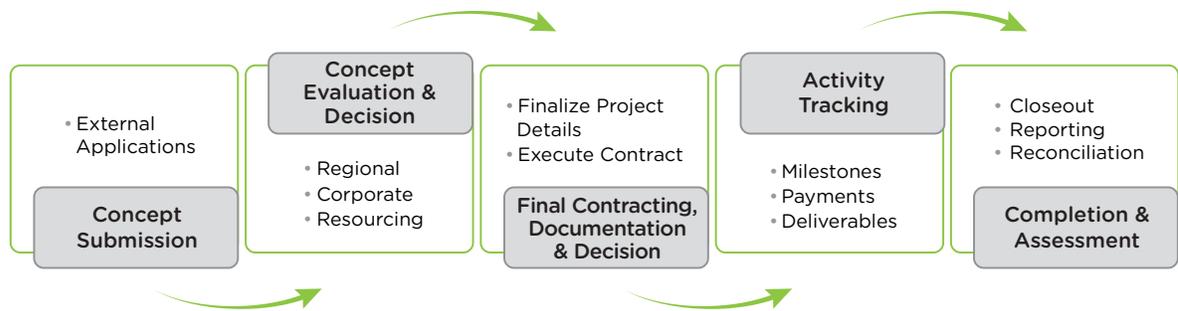
Details of the processing as defined by the business. Able to clearly define steps and actions needed.

Work Instructions: GBU #3

Details of the processing as defined by the business. Able to clearly define steps and actions needed.

Step 3: Process design

Schematic development of the process is needed to clearly identify the steps of the process. Using the policy as a guide, the development of the actual process was easily performed. For most activities there are five distinct steps from concept to completion, as follows.



Concept Submission

Conduits for external support requests may vary greatly throughout a large multinational organization. Both internal and external funding requests can compete for the same resources. Having the ability to visualize, evaluate, and understand the impact of each investment is important; refining the evaluation process is critical. Web-based submission portals linked to corporate Web sites have greatly improved submission processing—for both requester and reviewer. Information can be provided to prospective applicants as to what can be expected throughout the process and review requirements. In addition, prospective applicants can learn what is strategically important to the company, allowing self-assessment prior to submission. For companies, providing this type of information publicly can greatly improve the request quality in a compliant manner by reducing the volume and by improving alignment of external applications. From an external user's standpoint the Web portal provides a common point of interaction for multiple activities across a global organization, thereby simplifying and improving their experience throughout the process.

Evaluation and Decision

Concept review and approval are two of the most important steps of the process. It is critical that sound, strategically relevant requests are approved to move forward quickly. Visiontracker is configured to provide the appropriate amount of information at the appropriate time in the process through priming questions, allowing review committees to assess each application efficiently. Several critical items should be assessed—scientific merit, appropriate funding request, conflicts of interest, resource availability, ability to complete in a timely manner, and strategic alignment. In a global organization, alignment of these points is difficult with disparate processes. By adopting a common process and global system for use throughout the organization, improved visibility and activity efficiencies are realized. Regional approvals for local strategic alignment, budget allocation, and resource availability should be obtained prior to corporate approval and can be incorporated into the process easily. Standing meetings are easily scheduled for review committees, improving efficiencies, quality, and throughput.

Contracting Documentation and Final Decision

Upon concept approval the work begins. The applicant must complete the proposal to gain approvals from their organization and regulatory authority to conduct the proposed activity. Final negotiations of budgets, resources, and contracting are conducted and are tracked closely based on initial time estimates. Upon submission of completed documentation, final approval can be obtained by the appropriate regional and corporate committees. The globally aligned, appropriately sized activity is now ready to start. Approved regional resources can be utilized to help move these activities forward through internal and external processes.

Activity Tracking

Regional clinical activities are the responsibility of the regions to fund, resource, and track. Reporting rollup to corporate is a requirement to drive effective oversight of compliant activities and to ensure alignment of strategic initiatives. Upon contract execution, activities commence. Typically, a milestone payment is made at this point to provide seed funding. The amount of this payment is directly related to the activities projected to occur between the first and second milestone payments. Initial payment is clearly defined in the contract along with the other milestones and payments. For example, typical ISR milestones are contract execution, first patient in, last patient in, and publication. Budget allocations and financial responsibilities are determined prior to the start of any activity. Dates are clearly defined in the contract as to when these activities are to be completed. Maintaining internal and external expectations with respect to activity performance is critical throughout the life of the process. Defining clear, easy-to-follow steps is important to maintaining expectations. Visiontracker is configured to meet this need. Resource identification and assignment is facilitated through the implementation of a resource matrix that allows for automatic notification of workflow tasks and to facilitate internal/external communications. As activities progress, notifications for regular progress updates,

milestone tracking, and payments are automatically sent by Visiontracker. All of these components are tracked, maintained, and stored in Visiontracker for reporting, auditing, and project management.

Completion and Assessment

Upon completion of the contracted activities (includes successfully and unsuccessfully), closeout documentation and assessments are required. Successfully completed activities must include a final report of results and reconciliation of all budget items. A review of activities should be conducted internally to ensure that all contractually obligated activities have been completed and that final payments can be made. Communications are sent to all responsible parties to ensure appropriate notifications have been made and finalized. Upon confirming that all contracted items have been completed, the activity can be closed. Unsuccessfully completed activities include applicant withdrawal, inability to maintain contractual commitments or support cancellation by the business, requiring proper documentation. Alignment in the business unit is essential; communication to all stakeholders is required prior to closeout. This communication must include a summary of activity, who has been involved, rationale for closing, next steps, and timing. Although difficult at times, quickly closing unsuccessful activities allows reallocation of limited resources to activities with greater probability of success. Visiontracker facilitates effective management, review, and data storage. All regional activities are conducted with regional resources, reporting final decisions and results to corporate.

Step 4: SOP development

Upon completion of design and initiation of implementation processes, SOP development commenced. SOP development was used as an organizational cultural alignment activity that did vary among franchises, regions, and departments. Processing details, descriptive language, and interpretation were addressed at each step of the process. As a note; SOP language should be clear, simple, and succinct, defining roles and responsibilities. The system was intended to be rolled out globally, so insight into the global organization and its varied structures was reviewed prior to creating the final document. Focus was placed on system activities to align it's needs with qualified individuals. Job descriptions did vary across the organization, so system roles did not match every job titles. It was decided that It was more important to have the right person in the correct role than job title alignment. To this point, SOP processes, roles, and responsibilities were intended to be flexible, yet provide the appropriate structure that can easily be adopted across the organization. More than one SOP was needed to adequately define the process for each region and activity. A general SOP had been developed to summarize the process for the entire organization, in support of this, local SOPs defining the details for that particular business or region were developed and implemented.

Step 5: System rollout

Visiontracker was launched in a stepwise fashion based on regional needs, allowing an initial test period of the system to assess function, resourcing, and training. The United States was the first to gain access to the system. This decision was based on resource availability, familiarity with existing practices, and volume of existing and potential requests. The duration of this run-in period was three months. During this time, the clinical affairs teams became familiar with the tool, evaluated the new process, made refinements to their internal activities, and loaded the current ongoing activities into the system. Next, EU applicants were allowed access to Visiontracker due to business need and resource availability. Regional reviews, original part of the workflow design, were conducted for the first time prior to corporate scientific merit, compliance review, and decision. Asia Pacific followed by three months, again due to resource availability and business need. Currently, Latin America and emerging regions are pending Visiontracker access because of resourcing and request volume. It is expected that these regions will be rolled out in this calendar year.

Conclusion

The implementation of a global activity management system such as Visiontracker is a major undertaking. To reduce the complexity the components of design, development, and implementation processes need to be broken into smaller segments to simplify project management. From conception to completion this project took over one year to complete. Business alignment, team assembly, identification of best practice, policy, and initial process development took six months to complete. It is critical to get these steps right; the more time allotted to initial conceptual activities improves the end product and smooth's the implementation process. The global rollout of any activity management system such as Visiontracker needs to be assessed carefully and should be based on resource availability and business need. Cultural differences exist across the globe and need to be managed carefully. Creating a simple, compliant, flexible system is important, yet often is difficult to do in a large organization. A properly resourced, accountable team with decision-making authority is critical to success.

