

Implementation Process for the Intagras Tracking Portal.

intagras.

Intagras' Tracking Portal was created specifically for pharmaceutical companies by gathering requirements from pharmaceutical companies around the world. No assumptions are made that all companies are the same. Each implementation will start with a deep dive into current processes, procedures, and infrastructure using Six Sigma methodologies to ensure that your tracking portal fits seamlessly into your organization. The implementation plan and required tasks to be completed are available on day 1 on Monday.com which will provide constant visibility into the progress of the project for every level of your organization.

IMPLEMENTATION

The Intagras configuration process is broken down into six (6) phases which are described in detail below.

Phase 1 - Pre-Configuration

This usually takes between 2 weeks up to 6 months. Intagras will present the team with the largest configuration options in the system and the team will need to review the options and select the best fit. Intagras will provide details of all the options including pros and cons for each choice. A few meetings with Intagras will be necessary in the beginning to demonstrate the options and then I would expect a few follow up meetings to answer any questions.

Phase 2 - Building Blocks

Intagras will meet with the team for 2 hours, twice a week for four weeks to demonstrate and review options. Intagras will show the team the key functionality in the system that needs to be in place before the system can be used, and will provide details of the options and any pros and cons for the choices available. Intagras walks through all options in a demonstration environment to help the team become more familiar with the application and provide any IT staff with the location for the configuration items for future support.

If there are any questions on the options or how processes would best be configured in the system, Intagras will be available for ad-hoc meetings. The team will need meetings outside of the 2 meetings with Intagras each week to review the options and determine the best configuration options. Intagras has seen most teams dedicate at least 10 hours a week to the project at this phase.

Phase 2 - KPIs and Metadata

At this phase in the project, the team is invited to the Intagras demo site to begin using the software. Intagras will meet with the team for 2 hours, twice a week for two weeks. Intagras will walk the team through all of the functionality that will be required to report out status of all labeling changes (example: PSMF report). Intagras walks through all options in a demonstration environment to help the team become more familiar with the application and provide any IT staff with the location for the configuration items for future support.

If there are any questions on the options or how processes would best be configured in the system, Intagras will be available for ad-hoc meetings. The team will need meetings outside of the 2 meetings with Intagras each week to review the options and determine the best configuration options. Intagras has seen most teams dedicate at least 15 hours a week to the project at this phase. The team should be spending time in the Intagras demo site working through already completed labeling changes to try and find any missing data points that will need to be added.

Phase 4 - Functionality Options

Intagras will meet with the team for 2 hours, twice a week for 3 weeks to demonstrate functionality options. Intagras will present the functionality and explain all configuration options for each, as well as explain any pros and cons. Intagras walks through all options in a demonstration environment to help the team become more familiar with the application and provide any IT staff with the

location for the configuration items for future support.

If there are any questions on the options or how processes would best be configured in the system, Intagras will be available for ad-hoc meetings. The team will need meetings outside of the 2 meetings with Intagras each week to review the options and determine the best configuration options. Intagras has seen most teams dedicate at least 15 hours a week to the project at this phase. The team should be spending time in the Intagras demo site working through already completed labeling changes to try and find any missing data points that will need to be added.

In addition, the team should spend time reviewing the functionality options to determine if they are a good match for the current process.

Phase 5 - Alerts and Security

Intagras will meet with the team for 2 hours, twice a week for 1 week. During this time Intagras will work with the team to configure any email notifications that might be needed. Also, a full review of security options will be given. Intagras walks through all options in a demonstration environment to help the team become more familiar with the application and provide any IT staff with the location for the configuration items for future support.

The team is not expected to finalize the email notification options or the security options during this phase. Final configuration selections will be sent to Intagras no later than 1 week after the last training session.

At the end of Configuration Phase 5, Alerts and Security, Intagras will train all team members on how to use the Help Center from an end user's perspective. Access to the Intagras Help Center will be given at the end of the training. The Help Center has a library of functional demonstrations and write ups explaining use cases for

functionality.

Phase 6 - Team Testing & Training

This takes place in the Intagras demo environment and Intagras recommends spending as much time in this phase as possible. Intagras recommends no less than 4 weeks testing but 6-8 weeks would be better. Intagras will be available for ad-hoc meetings to answer any questions, or help run through any issues the team may be encountering. Intagras has seen most teams dedicate at least 15 hours a week to the project at this phase.

During Configuration Phase 6, Testing and Training, Intagras will host a meeting to on board support and testing staff. This training will include an overview of support, the enhancement request process, the software development life cycle, and information available in the Help Center for support staff. Intagras will also give training to support and testing staff on how to maintain the configured system, and how to troubleshoot issues.

When the team has completed their testing on the Intagras servers they will send an email to Intagras announcing the testing completion and that the team is ready to accept the configured database. Intagras will have ten (10) business days from that point to deliver the final configured database. This will be a backup copy of the database that can be loaded on to local servers for all environments, including production. During this ten (10) business day time frame, the team will not have access to any Intagras hosted systems.

At the end of this phase Intagras will provide a Site Administrator training course.

SUBMITTING IMPROVEMENT IDEAS

Intagras is dedicated to being the best tracking portal for pharmaceutical

companies. At the end of the implementation we ask you to submit enhancement requests for ways that the tracking portal can be improved to better meet your needs. Our software is made better every release by the continued ideas submitted by our clients and we can't wait to see how much better this software will be with yours.

DATA MIGRATION

Migration options are as follows:

Intagras assisted migration: data can be migrated from either a SQL database or an Excel spreadsheet. Intagras will provide a template for mapping so that the team can map what data gets migrated into the new system, and what fields it will be placed in. You will have the option to take a migration script that can be run in the environment, or to be handed a fully configured database with migrated data included. The fully configured database option is completed prior to go-live

Hand entered migration: your users (IT or business) can hand enter in data by using the User Interface of the system. This is done after go-live. Most clients do a "soft" go-live directly after validation so that select users can enter in migration data, and then do a full go-live to all users once the data migration is complete

DATA INTEGRATION AND BUSINESS LOGIC

Data Integration and business logic will be tailored for you to make sure the system meets all of your needs. Intagras can integrate with any system where the data is accessible to SQL Server by either table or view. Both incremental and cumulative updates are supported. To make sure your business gets the information you need at the correct time, Intagras can also schedule business logic and data integration to run independently at different intervals.



Intagras' tracking portals were designed specifically to meet the needs of the pharmaceutical and commercial labeling change process. Here's how we can help on these four keys to success:

Content Deviations

Local Operating Companies can request deviations to existing text changes, or request new text changes to be adding to an already existing version

Global Regulatory can review and approve or reject the request

Final text changes can be sent to dependent markets to decide if they would like to accept or reject the changes

Timeline Deviations

Record movement of due dates and update KPI status to indicate the due date has been changed

Country Dependencies

Countries that are dependent on another country's label will start in a waiting pattern until the reference country reaches health authority approval

Tracking Due Dates

Automatically track due dates based on the priority of a change (examples: safety, non-safety)

Track a level lower than due date KPI status by knowing how each country implemented, or did not implement

Add additional regulatory due dates to applicable changes, such as planned variations found through Eudravigilance data

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