

# NEW INNOVATIONS IN RMP TRACKING

Piers Rycroft

The difficulties with tracking the local implementation of Risk Management Plans (RMPs) and their local variations and commitments has long been an issue that pharma has struggled with. In this article, we address some of the customer-focused needs that have led to recent developments in bespoke RMP Tracking software.

## Background

From our experience, pharmaceutical companies are typically effective at tracking global or 'core' versions of their RMPs. However, tracking the status of local activities and milestones across all markets can be a compliance challenge. This is particularly important not only to ensure timely delivery of risk minimisation measures (RMMs) but also for compliance and audit readiness. At present, many pharmacovigilance (PV) teams across industry are reliant on manual systems built on top of passive tools, like spreadsheets and email, to manage their most critical data and processes.

Relying on these passive tools to give an up-to-date and reliable overview is an inspection and public health risk, as for these risk management activities, the stakes simply couldn't be higher. By using manual systems, activity and status data is often siloed in global departments or local affiliates, and prone to human error, resulting in poor version control and reliance on potentially out of date or incorrect information.

Many companies are now facing up to this issue and are moving to use dedicated software systems to track RMPs and their associated activities. With the ever-increasing number of drugs with complex RMPs entering the market, regulators at a national level have been seen to be increasing the level and number of their inspections of risk minimisation. By having a centralised source for this information that is also accessible to, and updated by local affiliates, global functions have easy access and oversight across all markets.

## Orbit: Tracking Software for Safety, PV and Regulatory

Since launching in 2013, Orbit has developed a suite of Regulatory, Pharmacovigilance, and Safety software products. They specialize in providing secure and validated systems, that help companies mitigate risk and enhance visibility across their business functions. All of their offerings can be hosted on-premise or on cloud-based services, which allows for scalability, and implementations 50% faster than industry averages for validated solutions.

By using Orbit's dedicated RMP Tracking software users will not only receive the benefits of using the software to track their RMP commitments, but also be part of a user network for continuing product development and support. Users will continuously have access to the most updated software ensuring compliance with future and more vigilant regulations.

## Track PV commitments through the product life-cycle

### Pre-launch activities

|  | Email and Spreadsheets   | Orbit RMP Tracker   |
|--|--|---|
| <b>Tracking risks and agreements on their management in development phases</b> | No single validated source of information on the decisions reached in proactive risk management by the Safety Management Team.<br>Risk of variability in the approaches to, and statements made on, risk management across all involved functions. | A single, validated, location into which all risk management decisions and activity agreements can be stored.<br>Easy access to all functions across the business to remove the risks of variability and re-invention.<br>Building block for the development of the submission RMP. |
| <b>Planning and development of Local RMPs</b>                                  | 100's of hours to generate and verify accuracy of Local plans in preparation for launch.   | Immediate access to all existing RMP templates for all products.<br>Easily generate local versions.<br>Edit and compare versions side-by-side .<br>Audit trail of edits to capture local variations and version details of Local RMPs.  |

### Post Marketing activities

|   | Email and Spreadsheets   | Orbit RMP Tracker  |
|---|--|--|
| <b>Ongoing project/ Team Management</b> | Limited oversight of global and local agreements on RMP related activities and studies e.g.<br>- Post Authorisation Safety studies<br>- Additional Risk Minimisation Measures (aRMM) | Capture local variations and version details of Local RMPs, and track pharmacovigilance commitments, activities and milestones across all markets and products. Local market teams can visualize required activities and milestones, and are sent reminders when timelines are missed. |
| <b>Audit Preparation</b>                | 100's of hrs spent preparing audit trails and verifying commitments have been met.   | Immediate access to all information on all RMPs without having to e-mail local subsidiaries and wait for their responses.<br>Creates, monitors, and audits your internal investigations of the RMP workflow whenever an activity doesn't meet a milestone, or goes off track.          |

## Continuous improvement and updates from a network of established users

Some of the Top 10 pharma companies are already using this system to ensure they are fully compliant and audit ready. Their feedback, on how the system is used in the real world, has been vital for the continuing development of this dedicated RMP Tracker software. Orbit uses this community of users to help them define the update priorities for their products, thus ensuring that they are completely aligned with the needs of users.

### Active notification of the 'right' information (Subscriptions)

With so much potential information being stored in one system it is important (for users to get the maximum benefit) that their own use of the system is properly customised to present them with the most relevant information for their role. Some of the most recent updates to version 3 of the system which was released in late 2017 include:

| Update                                  | Benefit   |
|---|---|
| Personal Subscriptions managed by User. | Each user can set up 'subscriptions' to a product or to activities affecting their role so that they are proactively informed when there's an update to RMPs that they have responsibility for. |
| Subscriptions managed by Global admin.  | Set-up 'push' notifications to all users in a defined group when updates to RMPs or the activities within them are saved in the system.   |
| Dedicated Commitments Page.             | View Activities and Milestones that you are responsible or accountable for in a single place.   |

## Improving usability and the user interface

| Update  | Benefit   |
|---|---|
| Improved Granularity in version comparison interface.                       | Users can compare two versions of an RMP (v1 to v2 or core to local) to see the differences between them and thus assess the impact of changes.<br>It's important to understand different commitments in different markets to understand timeline impacts and to enable the Global team to have full oversight of whether local activities will meet Global risk management objectives. |
| No longer need to lock the whole RMP to update a milestone or activity.     | When editing a section of the RMP (e.g. the progress of a risk minimization activity) the rest of the RMP remains open for editing, enabling more efficient activities in the responsible teams.  |
| Flex Fields – new fields with no default label for additional data capture. | If the configurable fields in the core RMP tracker don't quite meet your needs, it's now possible to define additional fields to expand the scope of tracked contents.  |

## Improving and streamlining business processes

| Update   | Benefit   |
|--|---|
| Advanced Permissions in Settings Tab.                            | Set-up permissions for view and edit so that you can safely allow partner companies to use the tracker with no risk of them gaining access to product information that is not relevant to them.   |
| Update Responsible Person tool changes responsibilities in bulk. | Handover of responsibilities and oversight due to a change in company structure, job roles or individual product responsibilities, can be managed with the click of a button.   |
| Individual RMP records can have attachments and links.           | You can now attach files at the activity level in the tool and so quickly and easily share templates for tools or reports and equally easily collect back the responses from local companies. All in a fully validated document management system.<br>Share information quickly within the team without the need for email trails and the risk of sharing incorrect information.<br>The system can be aligned and integrated with existing document management systems to make this as easy and simple as possible. |
| Milestones and Activities have their own pages.                  | To reduce the volume of information in the main page for each RMP, you can now display activity and milestone information on dedicated pages.<br>This enables you to provide access to update these pages to those who are responsible for the activity (e.g. in your local Medical Affairs team) while protecting the rest of the RMP from inadvertent editing.  |
| QC Check Fields.   | Ensure consistency and capture the right information.<br>Prompt users to complete mandatory fields to speed up processes.   |

By using Orbit's dedicated RMP Tracking software users will not only receive the benefits of using the software to track their RMP commitments, but also be part of a user network for continuing product development and support. Users will continuously have access to the most updated software ensuring compliance with future and more vigilant regulations.



[huronconsultinggroup.com](http://huronconsultinggroup.com)

© 2018 Huron Consulting Group Inc. and affiliates. All Rights Reserved. Huron is a management consulting firm and not a CPA firm, and does not provide attest services, audits, or other engagements in accordance with standards established by the AICPA or auditing standards promulgated by the Public Company Accounting Oversight Board ("PCAOB"). Huron is not a law firm; it does not offer, and is not authorized to provide, legal advice or counseling in any jurisdiction.

18-0404