

## RISK MANAGEMENT

# Global strategy, local execution.

With Orbit, your Risk Management Commitments are under control: gain total oversight of global RMP obligations and variations.



### Powerful Oversight

Oversee all global Risk Documents (RMP, dRMP, REMS, etc.), and their variations in safety specifications, obligations, and more.



### aRMM Compliance

Dedicated workflows for additional Risk Minimization Measures (aRMM) harmonize local markets.



### Proactive Management

Ensure compliance with all RMP commitments using proactive activities, milestones, and reminders.

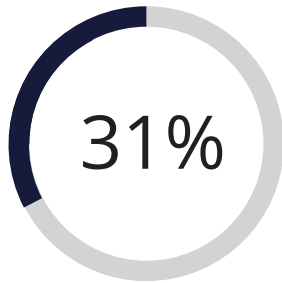
international  
coordination

Risk Management Plan Commitments require global coordination, collaboration and information sharing, making this one of the most complex and challenging processes in patient safety. Orbit is a proven solution for tracking Global and Local Risk Management Plans and their commitments, including Additional Risk Minimization Measures, in one system.

- RMP Tracker provides complete oversight of end-to-end RMP data, with dedicated tracking workflows for EU RMP, Core RMP, Developmental RMP (dRMP), local RMP, REMS, and aRMM.
- Additional Risk Minimization Measure implementation has never been easier than with Orbit -- global teams can create and distribute core materials, implementation plans, and localized tracking workflows to support local safety officers.
- Collect metrics from local safety officers to report seamlessly on total Risk Management system health, compliance, and effectiveness. Orbit helps compile this information into meaningful, actionable reports so your team is never left guessing on global risk commitments.

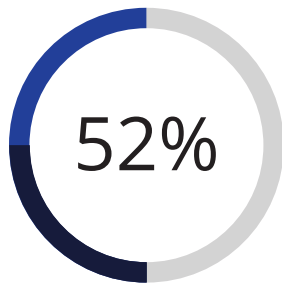
# Risk Management is too crucial for manual tools.

Using passive and manual tools, like spreadsheets and email, puts pharmaceutical companies at risk of miscommunication and error. Orbit enables users to store and transmit information easily, in one location, improving communication between team members and partners.



## MHRA Findings

Risk Management accounted for the majority of MHRA PV Inspection Findings (about 31%) between 2019-2020-- the third year in a row.<sup>1</sup>



## Additional Activities

Together, Additional PV and RM Activities accounted for about 52% of all Risk Management findings in the same MHRA report.<sup>1</sup>

1. Medicines & Healthcare products Regulatory Agency, *Pharmacovigilance Inspection Metrics Report: April 2019 - March 2020*, <<https://www.gov.uk/government/statistics/pharmacovigilance-inspection-metrics-2009-to-present>> [Accessed 13 October, 2021] (26 February 2021).

**Orbit automates global-to-local distribution of Risk Management Plans and Additional Risk Minimization materials.**


**By adding automation and centralizing oversight, Orbit improves overall RM system quality, speeds access to information, and supports increased local productivity.**


## About Orbit & Feith

From simple data capture through complex workflows and access rights, Orbit promises to change the way your company approaches workflow management.

For over 40 years, Feith has been committed to providing the most intuitive, versatile, user- friendly next generation solutions to highly regulated industries.

**Get  
In Touch.**

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