

Achievements and impact of the MLM service

A retrospective review of the first
10 years

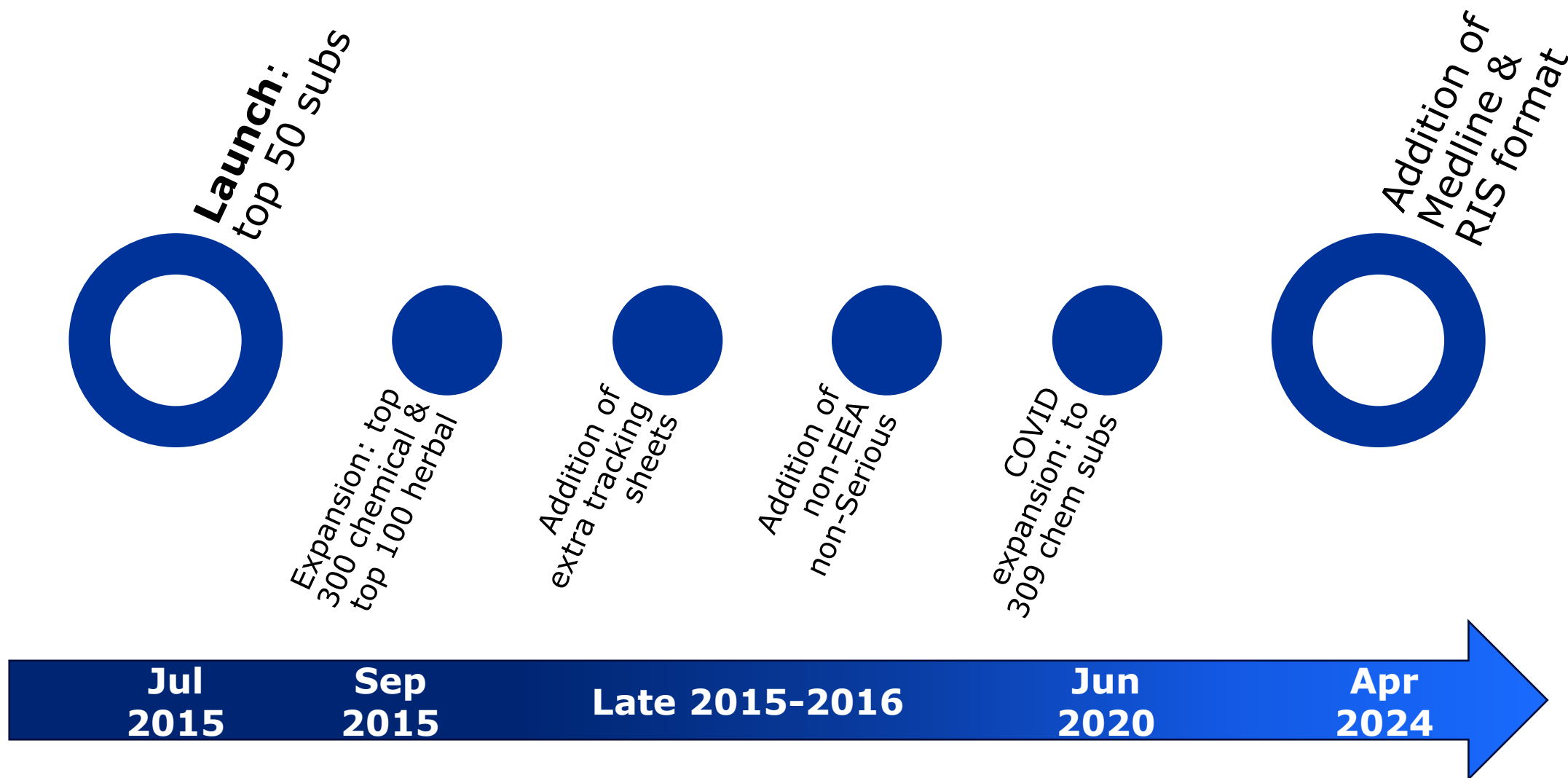
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History of the MLM Service



The MLM Service is 10

- In the first 10 years of operation, the MLM Service has:
 - Performed **1,520,168** searches
 - Screened & reviewed **5,922,061** articles
 - Translated **5,736** articles
 - Published **5,460** tracking sheets



The MLM Service is 10

- In the first 10 years of operation, the MLM Service has:
 - Made **58,092** individual cases
 - Submitted **101,145** ICSRs to EV
 - One for each case, plus follow-up
 - **80,954** serious
 - **96.3%** transmitted by day 7
 - **20,191** non-serious
 - **92.3%** by day 21



Benefits of the MLM Service

- The work the MLM Service performs on behalf of MAHs has saved industry from having to make over 140,000 ICSRs (90,000 cases) from the EEA alone
 - For the MLM Service, the ratio of non-EEA to EEA cases is 3:1
 - For the MLM Service, the ratio of non-EEA to EEA ICSRs is 2.6:1
 - If these ratios persist in the number of duplicate cases prevented, then MAHs would have been saved from having to make 560,000 ICSRs, referring to 324,000 cases

MLM Updates

- 2 minor updates related to MLM Service coming soon:
 - Regular **stakeholder survey** to be launched this month
 - All NCAs & MLM-MAHs will be contacted and asked for their views of the MLM Service
 - Substance group lists to be **updated in 2026**
 - The substance groups will stay the same, but the substances & combinations under them will be updated to reflect the latest data in the xEVMPD
 - EMA will write to all concerned MAHs with the new list 6 months before it comes into operation

Future enhancement

- In order to simplify the process of downloading the ICSRs created by the MLM Service EMA is building an **MLM-API**
- This will enable MAHs to programmatically download the MLM Service cases without the need for human intervention
- This will be particularly useful for those MAHs who have different portfolios of products in different territories and so need to make multiple different downloads each day
- The MLM-API will mirror the functionalities of the current manual download, but without the need for manual intervention or repeated downloading



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Thank you

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