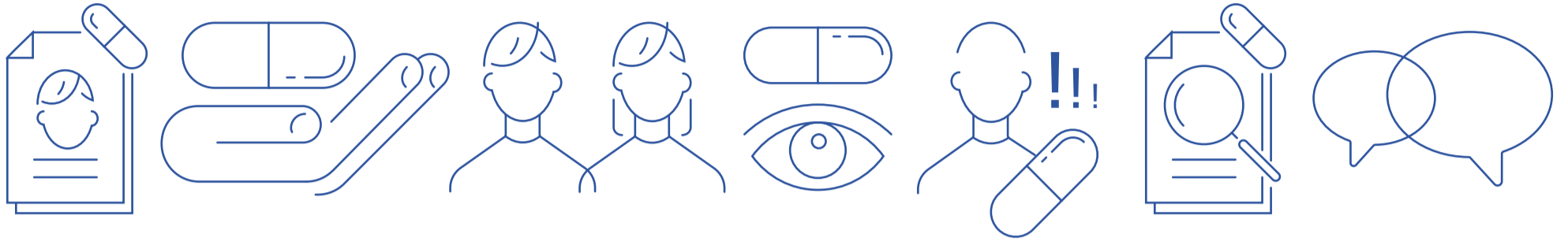




PRAC statistics

March 2022



7 Safety signals

- 3 Started
- 4 Ongoing and concluded

63 Periodic safety update reports (PSURs) single assessments

- 46 Recommendations for centrally authorised medicines only
- 16 Recommendations for nationally authorised medicines only
- 1 Recommendation for PSURs including both centrally and nationally authorised medicines

53 Risk management plans (RMPs) for centrally authorised medicines

- 11 RMPs reviewed for new medicines
- 42 RMPs reviewed for authorised medicines

32 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 3 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 16 | Protocols for non-imposed studies reviewed | 12 | Results from non-imposed studies reviewed |

0 Referrals

- 0 Started
- 0 Ongoing