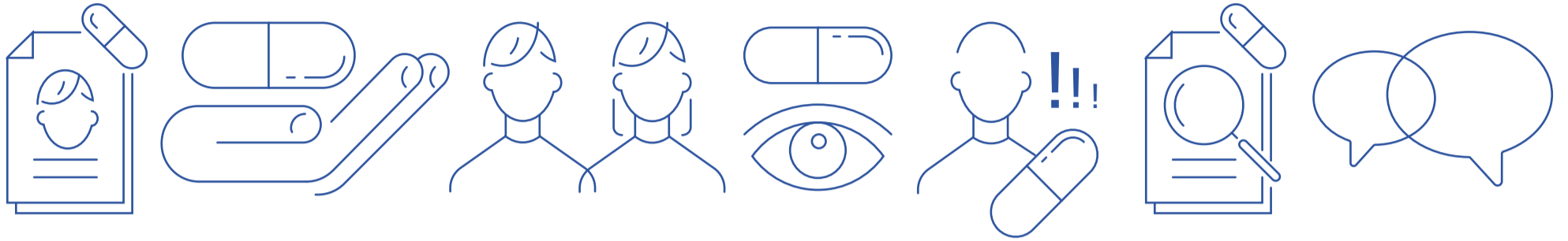




PRAC statistics

May 2022



3 Safety signals

- 2 Started
- 1 Ongoing and concluded

44 Periodic safety update reports (PSURs) single assessments

- 32 Recommendations for centrally authorised medicines only
- 6 Recommendations for nationally authorised medicines only
- 6 Recommendation for PSURs including both centrally and nationally authorised medicines

48 Risk management plans (RMPs) for centrally authorised medicines

- 13 RMPs reviewed for new medicines
- 35 RMPs reviewed for authorised medicines

37 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 2 | Protocols for imposed studies reviewed | 2 | Results from imposed studies reviewed |
| 25 | Protocols for non-imposed studies reviewed | 8 | Results from non-imposed studies reviewed |

1 Referral

- 0 Started
- 1 Ongoing