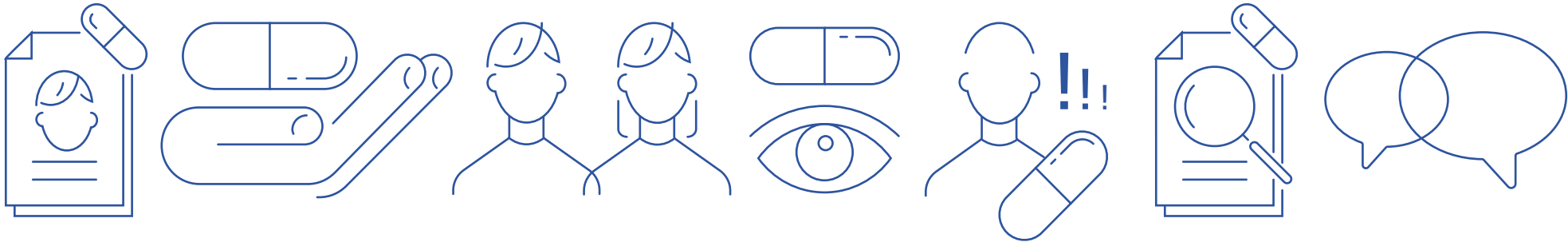




PRAC statistics

July 2022



6 Safety signals

- 4 Started
- 2 Ongoing and concluded

63 Periodic safety update reports (PSURs) single assessments

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

63 Risk management plans (RMPs) for centrally authorised medicines

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

32 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 3 | Protocols for imposed studies reviewed | 0 | Results from imposed studies reviewed |
| 18 | Protocols for non-imposed studies reviewed | 11 | Results from non-imposed studies reviewed |

2 Referrals

- 0 Started
- 2 Ongoing and concluded