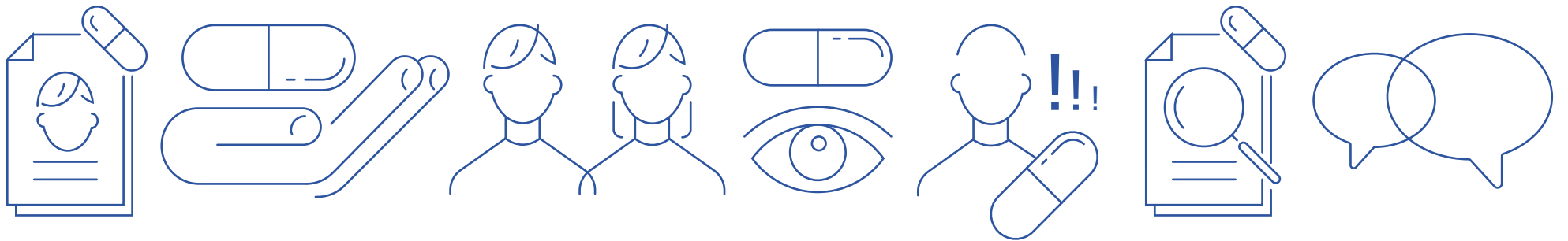




PRAC statistics

February 2022



8 Safety signals

- 4 Started
- 4 Ongoing and concluded

73 Periodic safety update reports (PSURs) single assessments

- 47 Recommendations for centrally authorised medicines only
- 23 Recommendations for nationally authorised medicines only
- 3 Recommendations for PSURs including both centrally and nationally authorised medicines

48 Risk management plans (RMPs) for centrally authorised medicines

- 10 RMPs reviewed for new medicines
- 38 RMPs reviewed for authorised medicines

26 Post-authorisation safety studies (PASSs)

- | | | | |
|---|--|---|---|
| 5 | Protocols for imposed studies reviewed | 3 | Results from imposed studies reviewed |
| 9 | Protocols for non-imposed studies reviewed | 9 | Results from non-imposed studies reviewed |

2 Referrals

- 1 Started
- 1 Ongoing