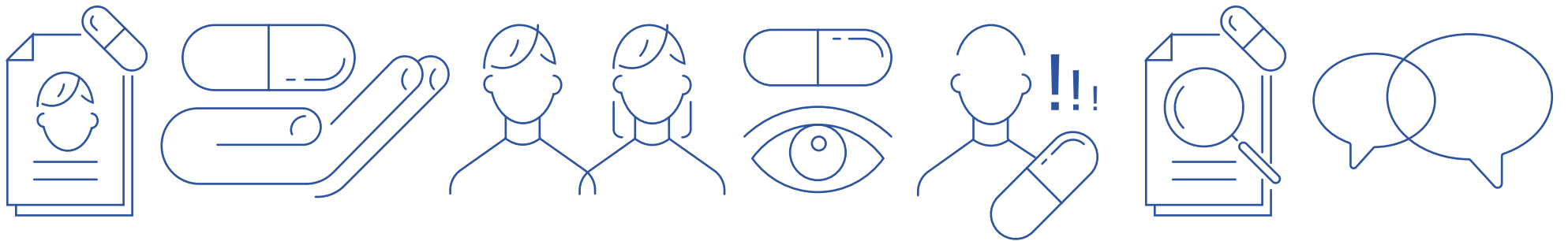




PRAC statistics

January 2022



8 Safety signals

- 4 Started
- 4 Ongoing and concluded

100 Periodic safety update reports (PSURs) single assessments

- 65 Recommendations for centrally authorised medicines only
- 31 Recommendations for nationally authorised medicines only
- 4 Recommendations for PSURs including both centrally and nationally authorised medicines

48 Risk management plans (RMPs) for centrally authorised medicines

- 12 RMPs reviewed for new medicines
- 36 RMPs reviewed for authorised medicines

30 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 7 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 13 | Protocols for non-imposed studies reviewed | 9 | Results from non-imposed studies reviewed |

1 Referral started