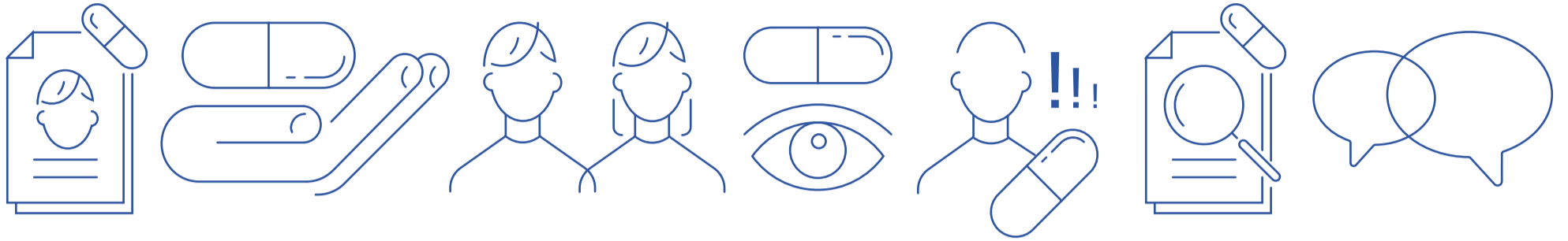




# PRAC statistics

May 2023



## 11 Safety signals

- 7 Started
- 4 Ongoing/concluded

## 60 Periodic safety update reports (PSURs) single assessments

- 37 Recommendations for centrally authorised medicines only
- 19 Recommendations for nationally authorised medicines only
- 4 Recommendations for PSURs including both centrally and nationally authorised medicines

## 60 Risk management plans (RMPs) for centrally authorised medicines

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

## 27 Post-authorisation safety studies (PASSs)

- |    |  |   |   |
|----|--|---|---|
| 5  | Protocols for imposed studies reviewed     | 1 | Result from imposed studies reviewed      |
| 13 | Protocols for non-imposed studies reviewed | 8 | Results from non-imposed studies reviewed |

## 2 Referrals

- 1 Started
- 1 Ongoing/concluded