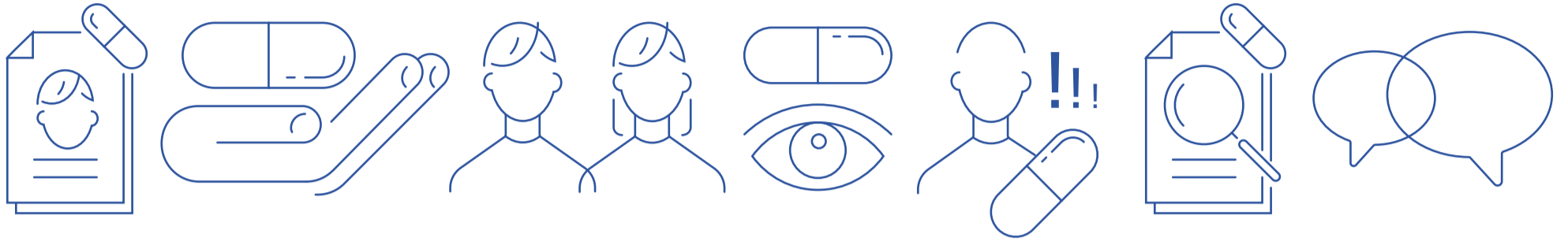




# PRAC statistics

June 2023



## 5 Safety signals

- 3 Started
- 2 Ongoing/concluded

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

- 45 Recommendations for centrally authorised medicines only
- 13 Recommendations for nationally authorised medicines only
- 3 Recommendations for PSURs including both centrally and nationally authorised medicines

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

- 5 RMPs reviewed for new medicines
- 47 RMPs reviewed for authorised medicines

## 35 Post-authorisation safety studies (PASSs)

- |    |  |   |   |
|----|--|---|---|
| 3  | Protocols for imposed studies reviewed     | 1 | Result from imposed studies reviewed      |
| 23 | Protocols for non-imposed studies reviewed | 8 | Results from non-imposed studies reviewed |

## 1 Referral

- 0 Started
- 1 Ongoing/concluded