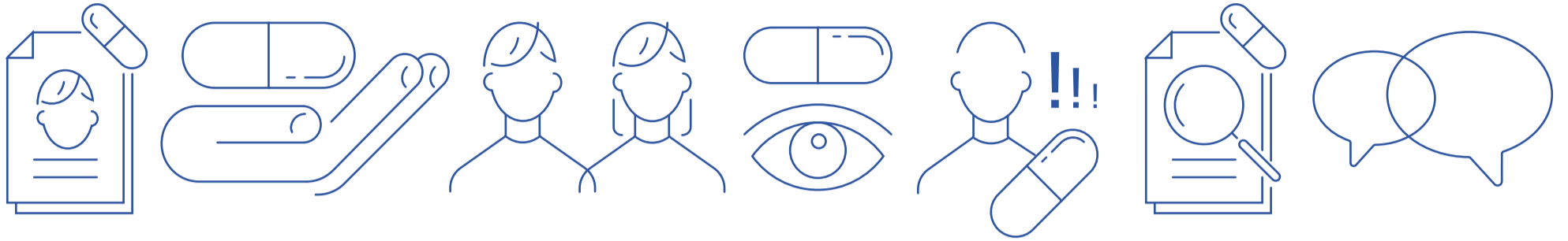




# PRAC statistics

June 2021



## 11 Assessments of safety signals for medicines

- 6 Started
- 5 Ongoing and concluded

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

- 85 Recommendations for centrally authorised medicines only
  - 29 Recommendations for nationally authorised medicines only
  - 4 Recommendations for PSURs including both centrally and nationally authorised medicines
- 
- 9 led to a change in the product information
  - 109 led to no changes

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

- 13 RMPs reviewed for new medicines
- 51 RMPs reviewed for authorised medicines

## 31 Post-authorisation safety studies (PASSs)

- |    |  |   |   |
|----|--|---|---|
| 6  | Protocols for imposed studies reviewed     | 0 | Results from imposed studies reviewed     |
| 16 | Protocols for non-imposed studies reviewed | 9 | Results from non-imposed studies reviewed |

## 0 Referrals concluded