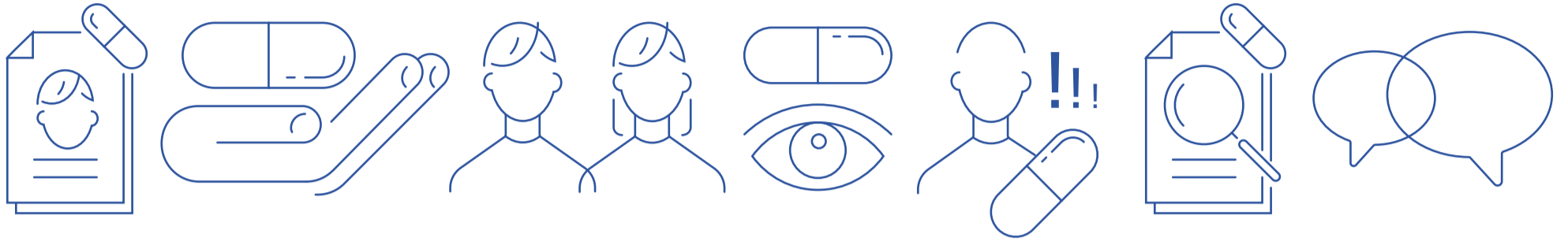




# PRAC statistics

October 2021



## 9 Assessments of safety signals for medicines

- 2 Started
- 7 Ongoing and concluded

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

- 52 Recommendations for centrally authorised medicines only
  - 20 Recommendations for nationally authorised medicines only
  - 9 Recommendations for PSURs including both centrally and nationally authorised medicines
- 
- 16 led to a change in the product information
  - 65 led to no changes

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

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

## 27 Post-authorisation safety studies (PASSs)

- |    |  |   |   |
|----|--|---|---|
| 3  | Protocols for imposed studies reviewed     | 4 | Results from imposed studies reviewed     |
| 11 | Protocols for non-imposed studies reviewed | 9 | Results from non-imposed studies reviewed |

## 0 Referrals concluded