



# GLASS SIX

# SIGNAL MANAGEMENT





# SIGNAL DETECTION

## TYPES

- Qualitative: Clinical Judgement  
(Inadequate/Limited information, Adequate but with confounders, signal index case)
- Quantitative: Disproportional statistics  
(ROR, EBOS)
- The act of looking for and/or identifying signals using the event data from any source





# SIGNAL DETECTION

Sources for the detection of signals can come from:

- spontaneous reporting
- active monitoring systems
- interventional studies (clinical trials)
- non-interventional studies (pharmacoepidemiology studies)
- non-clinical studies (e.g. animal toxicology studies)
- systemic reviews (i.e. thorough review of the published literature)
- meta-analyses (i.e. mathematical pooling of all the clinical trial data)
- other relevant sources.





# SIGNAL DETECTION

WHAT TO LOOK OUT FOR DURING SIGNAL DETECTION?

***Trends, frequency and severity amongst***

- SUSARs: Suspected Unexpected Serious Adverse Reactions
- DME: Designated Medical Events
- Fatal
- OFU: Off-Label Use
- Special populations: Elderly, Pediatrics, Pregnant Women, Lactation Mothers
- Product Quality



Task Number	Task Name	Start Date	End Date	Progress	Owner	Category	Sub-category	Priority	Status
1	Task 1	2023-01-01	2023-01-05	100%	John Doe	Development	Frontend	High	Completed
2	Task 2	2023-01-06	2023-01-10	50%	Jane Smith	Development	Backend	Medium	In Progress
3	Task 3	2023-01-11	2023-01-15	20%	Mike Johnson	Development	Frontend	Low	Pending
4	Task 4	2023-01-16	2023-01-20	80%	Emily White	Development	Backend	High	In Progress
5	Task 5	2023-01-21	2023-01-25	30%	David Brown	Development	Frontend	Medium	Pending
6	Task 6	2023-01-26	2023-01-30	60%	Alice Green	Development	Backend	Low	In Progress
7	Task 7	2023-01-31	2023-02-04	10%	Bob Black	Development	Frontend	High	Pending
8	Task 8	2023-02-05	2023-02-09	40%	Charlie Red	Development	Backend	Medium	In Progress
9	Task 9	2023-02-10	2023-02-14	70%	Diana Blue	Development	Frontend	Low	Pending
10	Task 10	2023-02-15	2023-02-19	90%	Ethan Yellow	Development	Backend	High	In Progress
11	Task 11	2023-02-20	2023-02-24	15%	Fiona Purple	Development	Frontend	Medium	Pending
12	Task 12	2023-02-25	2023-02-29	55%	George Grey	Development	Backend	Low	In Progress
13	Task 13	2023-03-01	2023-03-05	85%	Helen Silver	Development	Frontend	High	Pending
14	Task 14	2023-03-06	2023-03-10	25%	Ivan Gold	Development	Backend	Medium	In Progress
15	Task 15	2023-03-11	2023-03-15	65%	Judy Bronze	Development	Frontend	Low	Pending
16	Task 16	2023-03-16	2023-03-20	95%	Kyle Copper	Development	Backend	High	In Progress
17	Task 17	2023-03-21	2023-03-25	10%	Laura Nickel	Development	Frontend	Medium	Pending
18	Task 18	2023-03-26	2023-03-30	45%	Mark Zinc	Development	Backend	Low	In Progress
19	Task 19	2023-03-31	2023-04-04	75%	Nancy Tin	Development	Frontend	High	Pending
20	Task 20	2023-04-05	2023-04-09	35%	Oscar Lead	Development	Backend	Medium	In Progress