

Aggregate Reporting-Mid Level

S.No	Title	Total: 40 Hours
1	Introduction to Aggregate reporting	1 hour
2	Introduction, scope, terminology, frequency and timing of PSURs/PBRERs	3 hours
s3	Comparision of PSUR and PBRER	1 hour
4	GVP module VII/ICH E2C R2 guidelines	5 hours
5	PADER and PBRER Scheduling	3 hours
6	Data gathering	1 hour
7	PADER Template	2 hours
8	PBRER Template	4 hours
9	PBRER Submission	2 hour
10	Handling literature in aggregate reports	1 hour
11	Guide on contents of PSURs in special situations/addendum PSURs/Safety statement	2 hours
12	Introduction to Addendum to Clinical Overview (ACOs)	2 hours
13	Sections of ACO (including appendices)	3 hours
14	Signal detection	2 hours

15	Signal assessment	3 hours
16	Contents of DSUR as per guideline	5 hours