

Paper I, Clinical Research and Clinical Pharmacology – 100 questions

Paper II, Ethics, Guidelines and Regulations in Clinical Research – 100 questions

Paper III, Clinical Trial Management and Quality Management – 100 questions

Paper IV (a), Clinical Data Management and SAS / Pharmacovigilance – 100 questions (50 + 50)

Paper IV (b), Clinical Data Management and SAS –100 questions

Paper IV (c), Pharmacovigilance – 100 questions

Papers	Name of the Paper	Applicable to Course	Marks
Compulsory papers	Paper I, Clinical Research and Clinical Pharmacology –100 questions	Common for all students of ICBio	100
	Paper II, Ethics, Guidelines and Regulations in Clinical Research – 100 questions	For “Advance diploma in Clinical Research & Pharma Regulatory Affairs” *Only compulsory papers will be considered for this program	100
	Paper III, Clinical Trial Management and Quality Management – 100 questions		100
Optional Papers	Paper IV (a) , Clinical Data Management / Pharmacovigilance – 100 questions (50 + 50)	Post Graduate Diploma in Clinical Research and Clinical Data Management	100
	Paper IV (b) , Clinical Data Management and SAS –100 questions	Advance Diploma in Clinical Research and Clinical Data Management	100
	Paper IV (c) , Pharmacovigilance –100 questions	Advance Diploma / Post Graduate Diploma in Pharmacovigilance	100

Explanation for the Examination Scheme

There are a total of 5 programs/courses offered by ICBio.

Advance Diploma Programs include:

Advance Diploma in Clinical Research and Clinical Data Management, Paper I, II, III and IV (b)

Advance Diploma in Clinical Research and Pharma Regulatory Affairs, Paper I, II, III

Advance Diploma in Clinical Research and Pharmacovigilance, Paper I, II, III and IV (c)

Post Graduate Diploma Programs include:

Post Graduate Diploma in Clinical Research and Clinical Data Management, Paper I, II, III and IV (a)

Post Graduate Diploma in Clinical Research and Pharmacovigilance, Paper I, II, III and IV (c)

Marking Scheme:

* All questions carry 1 mark each.

* 1 mark will be awarded for each right answer.

*There is no negative marking.

* Each student will be evaluated for 400 marks except students for

“Advance Diploma in Clinical Research and Pharma Regulatory Affairs” which will be evaluated for 300 marks only.

For “Post Graduate Diploma in Clinical Research and Clinical Data Management “50 questions shall be provided from Paper IV (b) and paper IV (c) each. i.e. 100 questions in total

This Question bank consists of 500 questions for papers I, II, III, IV (a), IV (b) and IV(c) respectively.