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provides hundreds of questions and answers in the areas that will likely be covered on your upcoming exam including but not limited to administration office record keeping preparing written materia japan clinical trial regulatory process posted by trial expert there is an increase in interest for the drug developers to conduct clinical trials in japan due to huge market size clear regulatory guidelines a crisp approval process and other such factors this guideline was the first document in japan about the utilization of rwd by pharmaceutical industries it describes points to consider how pharmaco epidemiological studies are planned and designed for clinical safety assessment of a drug with the secondary use of medical information database in addition when conducting specific clinical trials a certified review board crb is required to inspect and approve the study and the study protocol must be submitted to the ministry of health labor and welfare as of july 1 2021 101 medical 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