The Plan

For the development of a Clinical Pharmacology Unit (CPU) or Clinical Research Unit (CRU) to carry out medical research in the early Drug Development period (Phase I and IIa)

Overview

The ideal clinical trial facility (CPU / CRU) would be set-up so that 1) any study of the early clinical drug / device development program including First-in-man, Drug metabolism, Dose finding, Pharmacokinetics, Organ system failure (renal or Hepatic), First-in-patient, Bioavailability, Bioequivalence, or even Thorough QT/QTc studies can be undertaken with a minimum of effort and 2) The data generated is integrated on-line with the automatic transfer (or as near to this as possible), compiling and reporting of study data. Central to the above is the overriding importance of the primacy of safeguarding the safety of subjects.

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