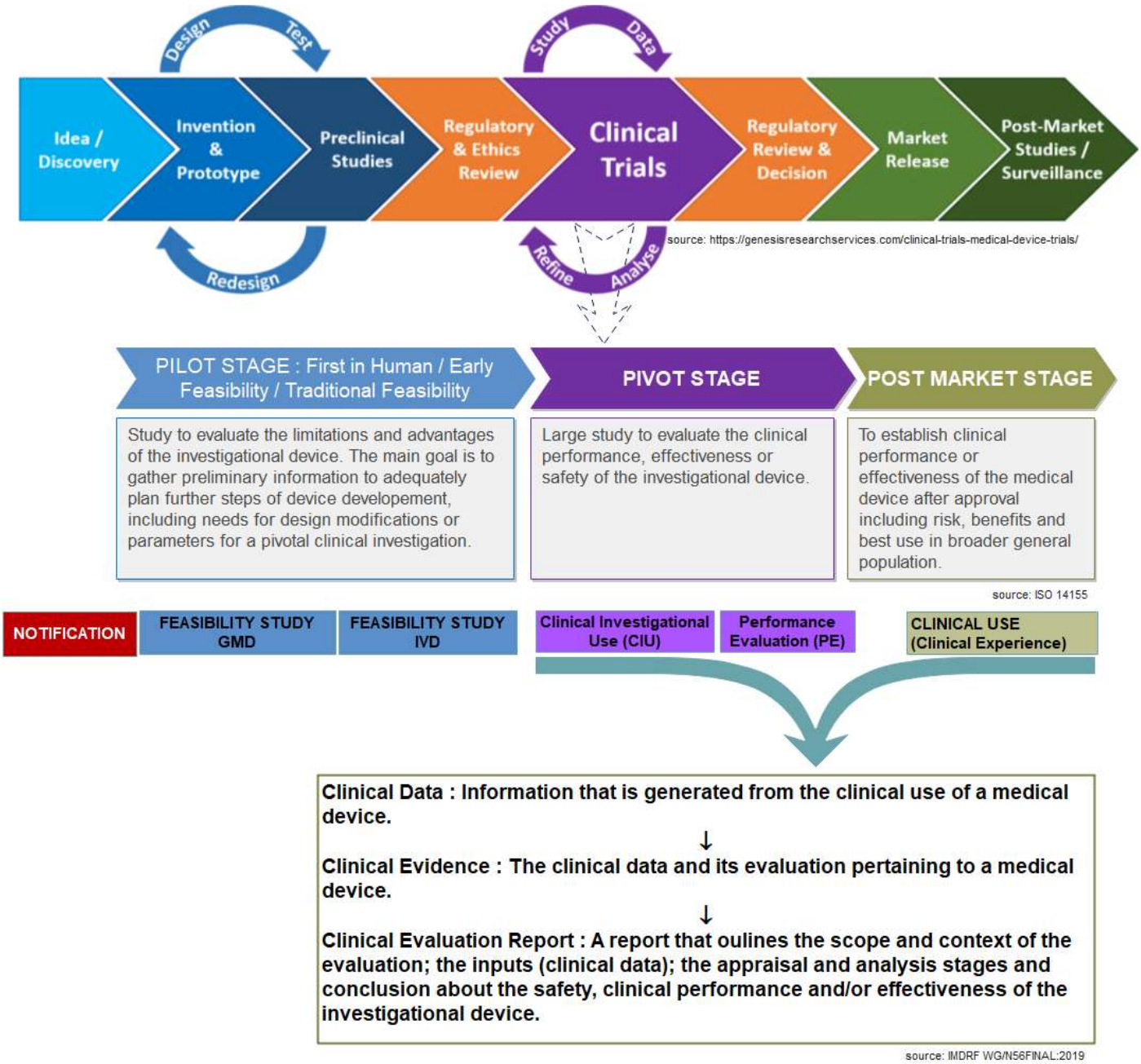
NOTIFICATION OF DEVICE STUDY (DS)

A. GENERAL IDEAS FOR CLINICAL TRIAL



B. DEVICE STUDY NOTIFICATION TYPE – TERMS & DEFINITION

DEVICE STUDY NOTIFICATION TYPE

Notification Clinical Investigational Use (CIU)	Notification Performance Evaluation (PE)	Notification Clinical Use (Clinical Experience) GMD & IVD	Notification Feasibility Study GMD & IVD
Systematic investigation on human subjects, undertaken to assess the safety, clinical performance and/or effectiveness of a medical device.	An assessment and analysis of data to establish or verify the scientific validity, the analytical and the clinical performance of an IVD device. To demonstrate the ability of an IVD device to achieve its intended purpose as claimed by the manufacturer.	*Post-market clinical follow-up study* A study carried out following marketing authorization intended to answer specific questions (uncertainties) relating to safety, clinical performance and/or effectiveness of a device when used in accordance with its labelling.	A study used to capture preliminary clinical performance, effectiveness or safety information of a near-finl or final device design to adequately plan an appropiate pivotal clinical investigation.
Source: IMDRF WG/N65FINAL:2021	Source: MDCG 2022-2	Source: IMDRF WG/N65FINAL:2021	Source: ISO 14155

Definition GMD & IVD

GENERAL MEDICAL DEVICE (GMD)

Any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of -
(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(iii) investigation, replacement or modification, or support of the anatomy or of a physiological process;
(iv) support or sustaining life;
(v) control of conception;
(vi) disinfection of medical device.

Medical device that other than those used for the in vitro examination of specimens derived from the human body.

Source: MDA/GD/0009

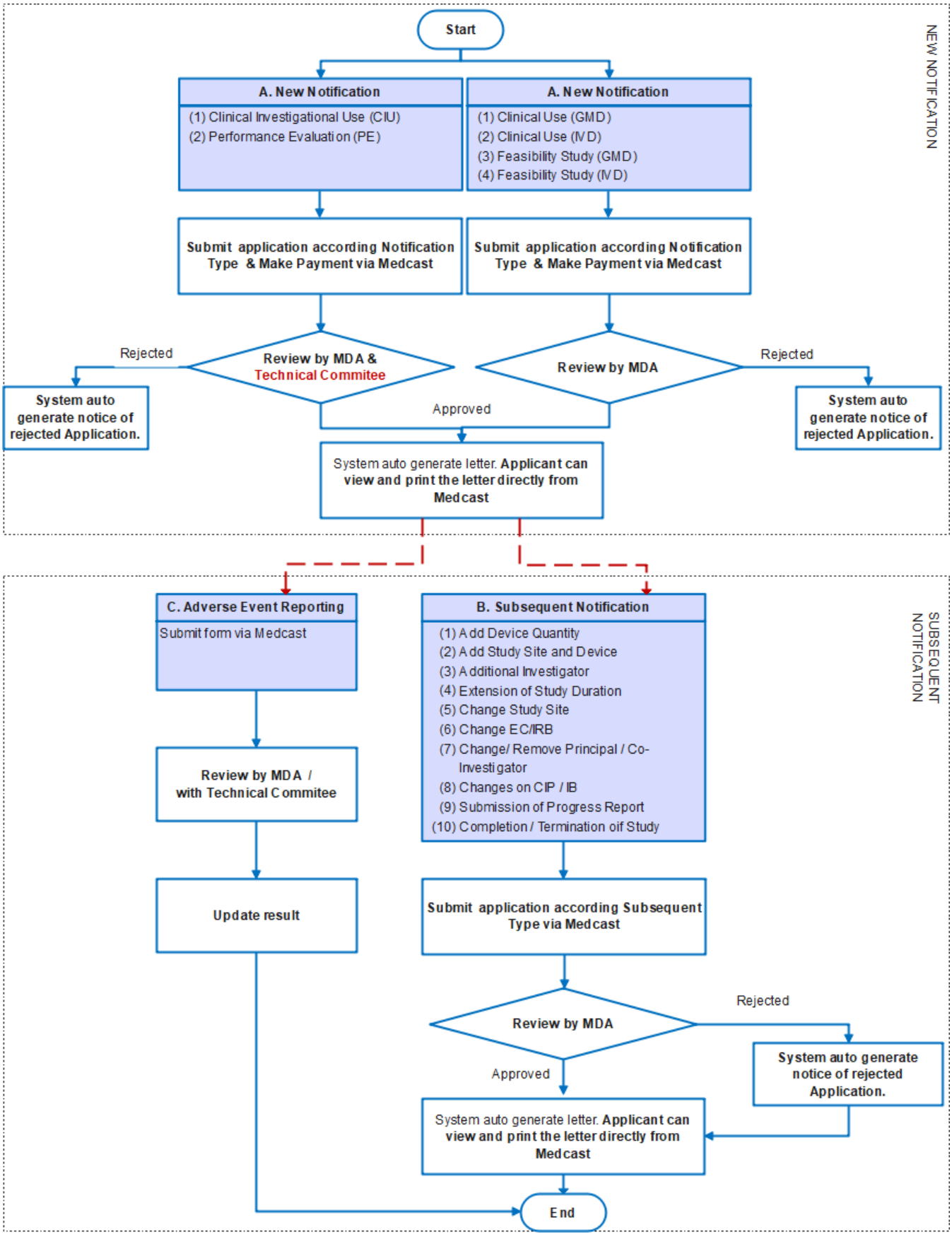
IN-VITRO DIAGNOSTIC (IVD)

In vitro diagnostic device are used for in vitro examinati on of specimens derived from the human body to provide information for screening, diagnosis, or treatment monitoring purposes.

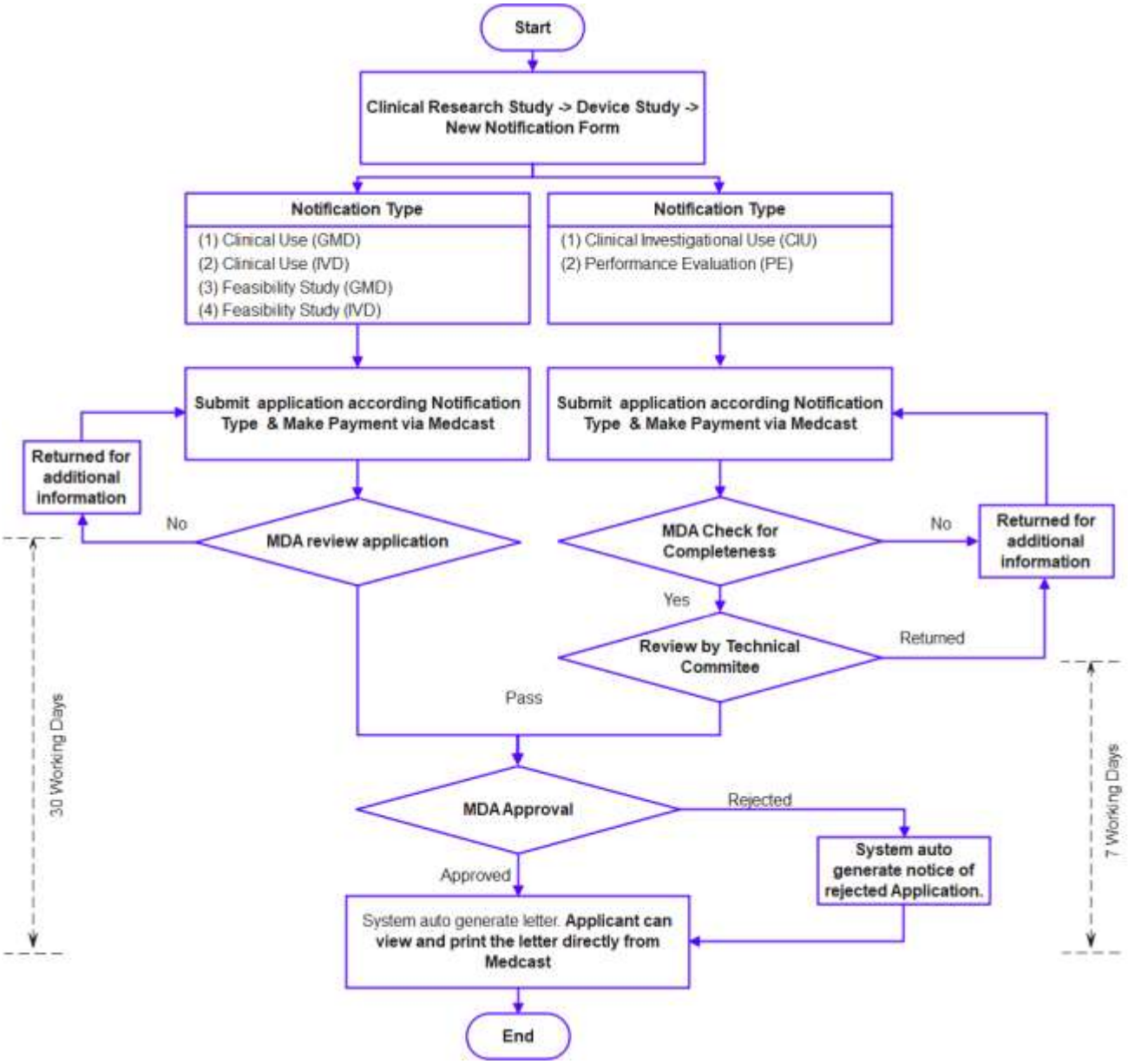
Includes any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its manufacturer to be used in vitro for the examination of any specimen, including
any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information:-
a) concerning a physiological or pathological state or a congenital abnormality
b) to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or
c) to monitor therapeutic measures; and includes a specimen receptacle.

Source: MDA/GD/0001

C. FLOW CHART PROCESS FOR OVERALL DEVICE STUDY NOTIFICATION



D. FLOW CHART PROCESS FOR MEDCAST NEW NOTIFICATION OF DEVICE STUDY (DS)



E. FLOW CHART PROCESS FOR MEDCAST SUBSEQUENT NOTIFICATION OF DEVICE STUDY (DS)