Medical Affairs Acronyms and Terminology

MSL: Medical Science Liaison KOL: Key Opinion Leader Also known as:

KEE-Key External Expert

TL-Thought Leader

OL-Opinion Leader

EE-External Expert

IIT: Investigator Initiated Trial

Also known as:

IST- Investigator Sponsored Trial

ISS- Investigator Sponsored Study

IIS- Investigator Initiated Study

ISR- Investigator Sponsored Research

SIV: Site Initiation Visit

PDUFA: Prescription Drug User Fee Act (often used to list "PDUFA dates")

NDA: New Drug Application

CRL: Complete Response Letter

GMA: Global Medical Affairs

HCP: Healthcare Provider

PI: Principal Investigator OR package insert

AE: Adverse Event

HEOR: Health Economics and Outcomes Research

RWE: Real World Evidence

CME: Continuing Medical Education

CRO: Clinical Research Organization

Ad Comm: Advisory Committee (group of experts giving independent opinions to FDA)

Ad Board: Advisory Board (group of thought leaders to help identify knowledge gaps and ways to address them in a particular field)