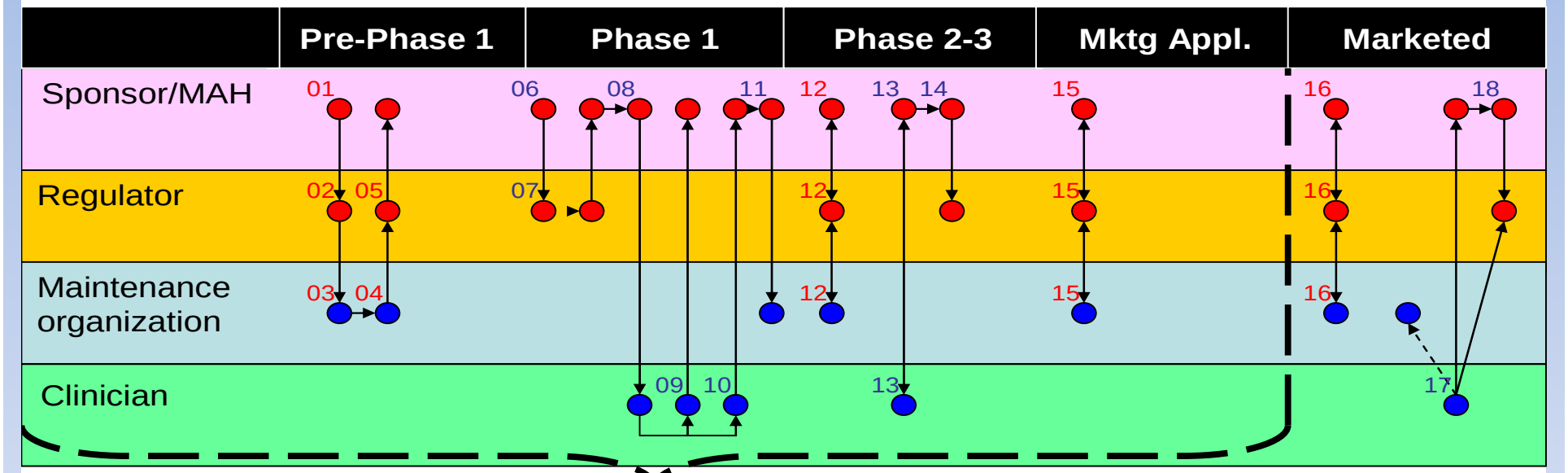
Potential Interactions During the Lifecycle of a Medicinal Product and contacts with the Maintenance Organization

Substances: Potential interactions during the lifecycle of a medicinal product

Key:
- Complete information supporting application
- Information required for the task only



01 Request new substance

02 Checks request & agrees

03 Checks request & assigns ID

04 Acceptance, ID & entry information communicated

05 ID & entry information communicated

06 Clinical trial application (includes substance ID)

07 Request reviewed & accepted

08 Protocol etc to investigator (using substance ID)

09 Investigator reports results (using substance ID)

10 Investigator reports AEs (using substance ID)

11 Sponsor reports AEs (using substance ID)

12 Steps 1 – 5 repeated for further details or specified substance

13 Repeat clinical process (steps 6-10; includes substance ID)

14 Sponsor reports AEs (using substance ID)

15 & 16 Steps 1 – 5 repeated for further details or specified substance

17 Clinician consults public substance DB and reports AEs to MAH and/or regulator

18 MAH reports AE to regulator.

19. Information handled under confidentiality arrangements. If already properly in the public domain, publication in line with agreed policy (TBD).