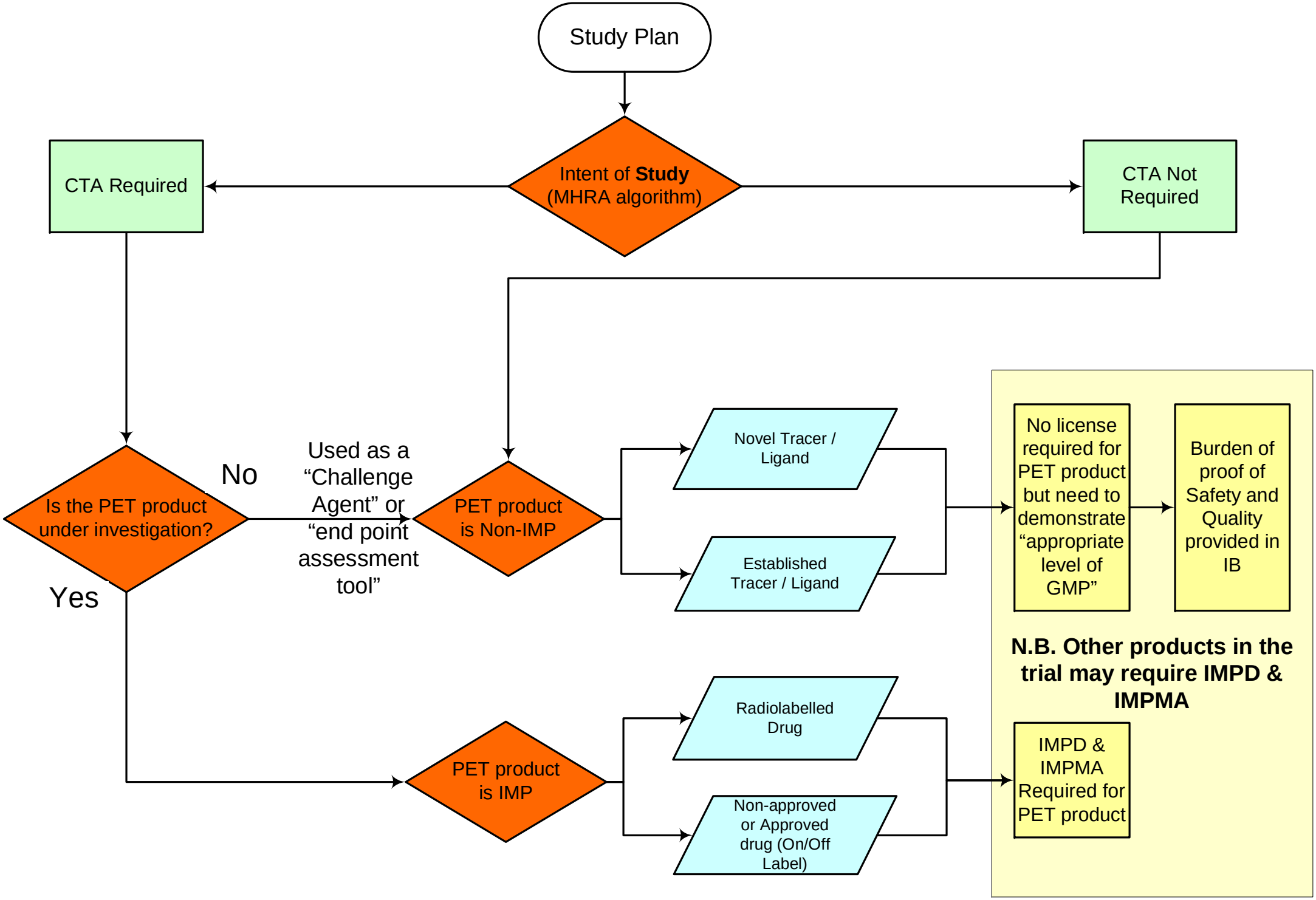
Study Plan
Intent of **Study** (MHRA algorithm)
CTA Required
CTA Not Required
Is the PET product under investigation?
No
Yes
Used as a "Challenge Agent" or "end point assessment tool"
PET product is Non-IMP
Novel Tracer / Ligand
Established Tracer / Ligand
No license required for PET product but need to demonstrate "appropriate level of GMP"
Burden of proof of Safety and Quality provided in IB
N.B. Other products in the trial may require IMPD & IMPMA
PET product is IMP
Radiolabelled Drug
Non-approved or Approved drug (On/Off Label)
IMPD & IMPMA Required for PET product