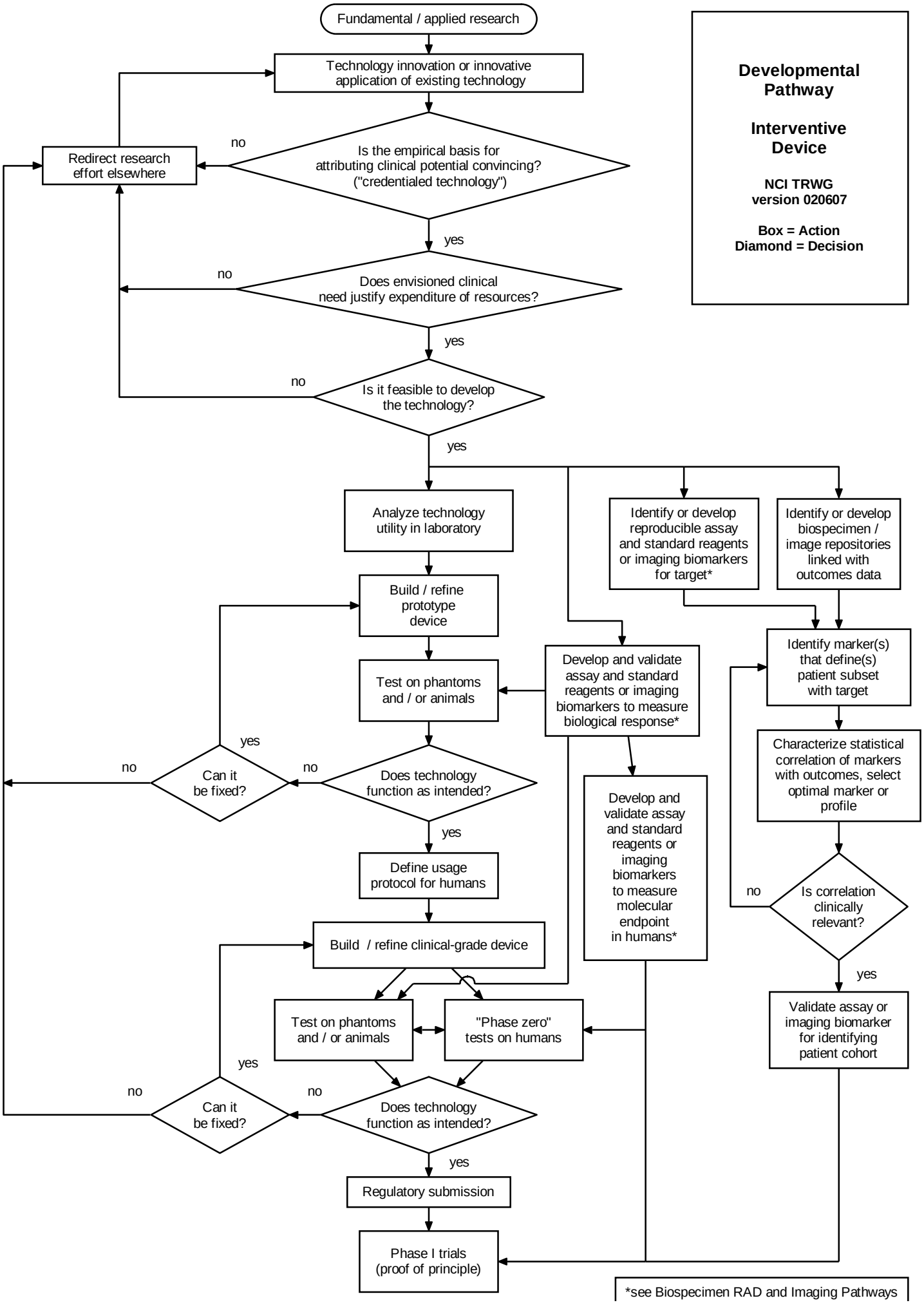
Developmental Pathway
Interventive Device
NCI TRWG
version 020607
Box = Action
Diamond = Decision
Fundamental / applied research
Technology innovation or innovative application of existing technology
Is the empirical basis for attributing clinical potential convincing? ("credentialed technology")
no
Redirect research effort elsewhere
yes
Does envisioned clinical need justify expenditure of resources?
no
yes
Is it feasible to develop the technology?
no
yes
Analyze technology utility in laboratory
Identify or develop reproducible assay and standard reagents or imaging biomarkers for target*
Identify or develop biospecimen / image repositories linked with outcomes data
Build / refine prototype device
Test on phantoms and / or animals
Develop and validate assay and standard reagents or imaging biomarkers to measure biological response*
Identify marker(s) that define(s) patient subset with target
Characterize statistical correlation of markers with outcomes, select optimal marker or profile
Does technology function as intended?
no
Can it be fixed?
yes
no
Develop and validate assay and standard reagents or imaging biomarkers to measure molecular endpoint in humans*
Is correlation clinically relevant?
no
yes
Define usage protocol for humans
Build / refine clinical-grade device
Test on phantoms and / or animals
"Phase zero" tests on humans
Validate assay or imaging biomarker for identifying patient cohort
Does technology function as intended?
no
Can it be fixed?
yes
no
yes
Regulatory submission
Phase I trials (proof of principle)
*see Biospecimen RAD and Imaging Pathways