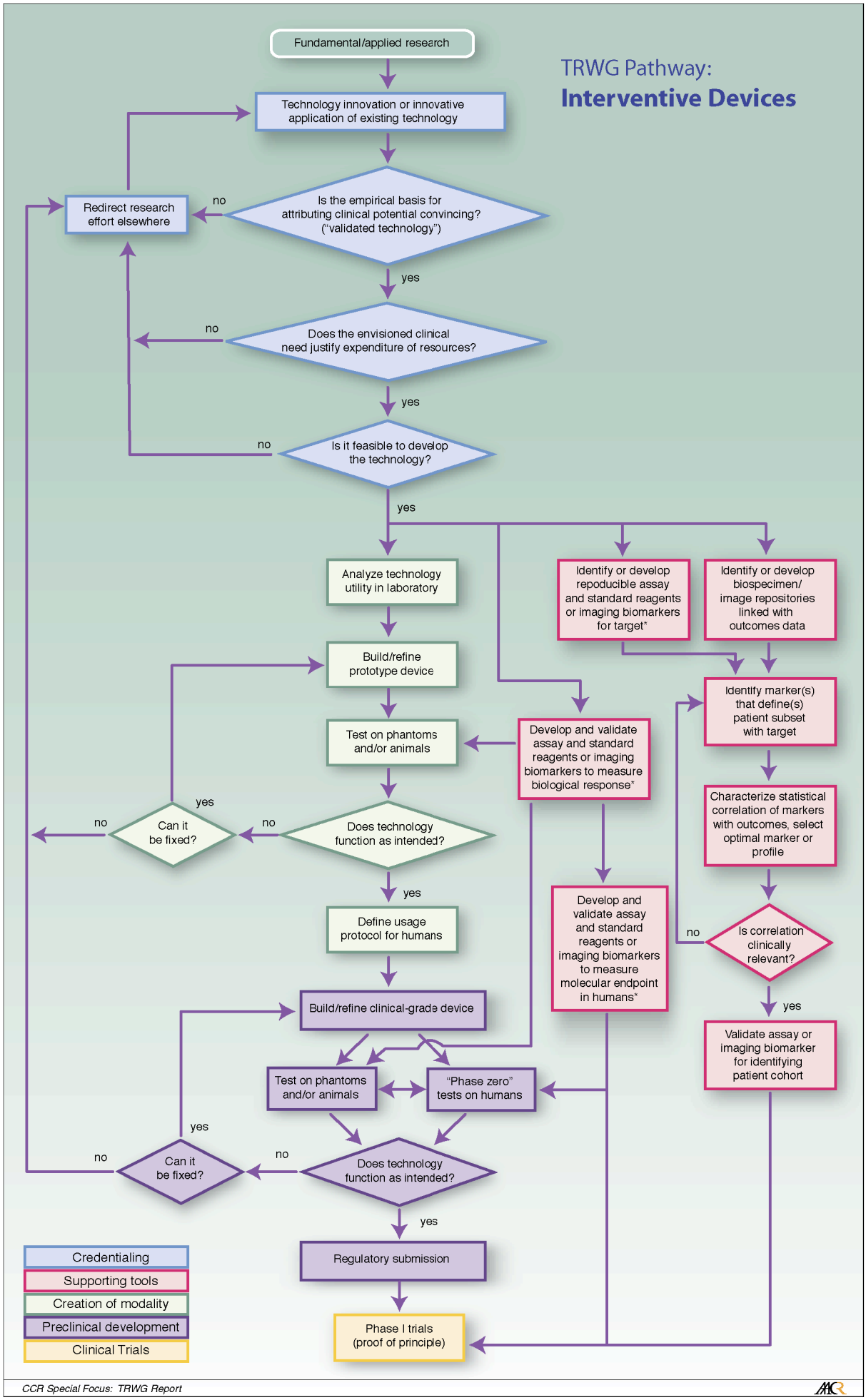
TRWG Pathway:
Interventive Devices
Fundamental/applied research
Technology innovation or innovative application of existing technology
Is the empirical basis for attributing clinical potential convincing? ("validated technology")
no
Redirect research effort elsewhere
yes
Does the envisioned clinical need justify expenditure of resources?
no
yes
Is it feasible to develop the technology?
no
yes
Analyze technology utility in laboratory
Build/refine prototype device
Test on phantoms and/or animals
Does technology function as intended?
no
Can it be fixed?
yes
no
yes
Define usage protocol for humans
Build/refine clinical-grade device
Test on phantoms and/or animals
"Phase zero" tests on humans
Does technology function as intended?
no
Can it be fixed?
yes
no
yes
Regulatory submission
Phase I trials (proof of principle)
Identify or develop repoducible assay and standard reagents or imaging biomarkers for target*
Identify or develop biospecimen/ image repositories linked with outcomes data
Develop and validate assay and standard reagents or imaging biomarkers to measure biological response*
Develop and validate assay and standard reagents or imaging biomarkers to measure molecular endpoint in humans*
Identify marker(s) that define(s) patient subset with target
Characterize statistical correlation of markers with outcomes, select optimal marker or profile
Is correlation clinically relevant?
no
yes
Validate assay or imaging biomarker for identifying patient cohort
Credentialing
Supporting tools
Creation of modality
Preclinical development
Clinical Trials