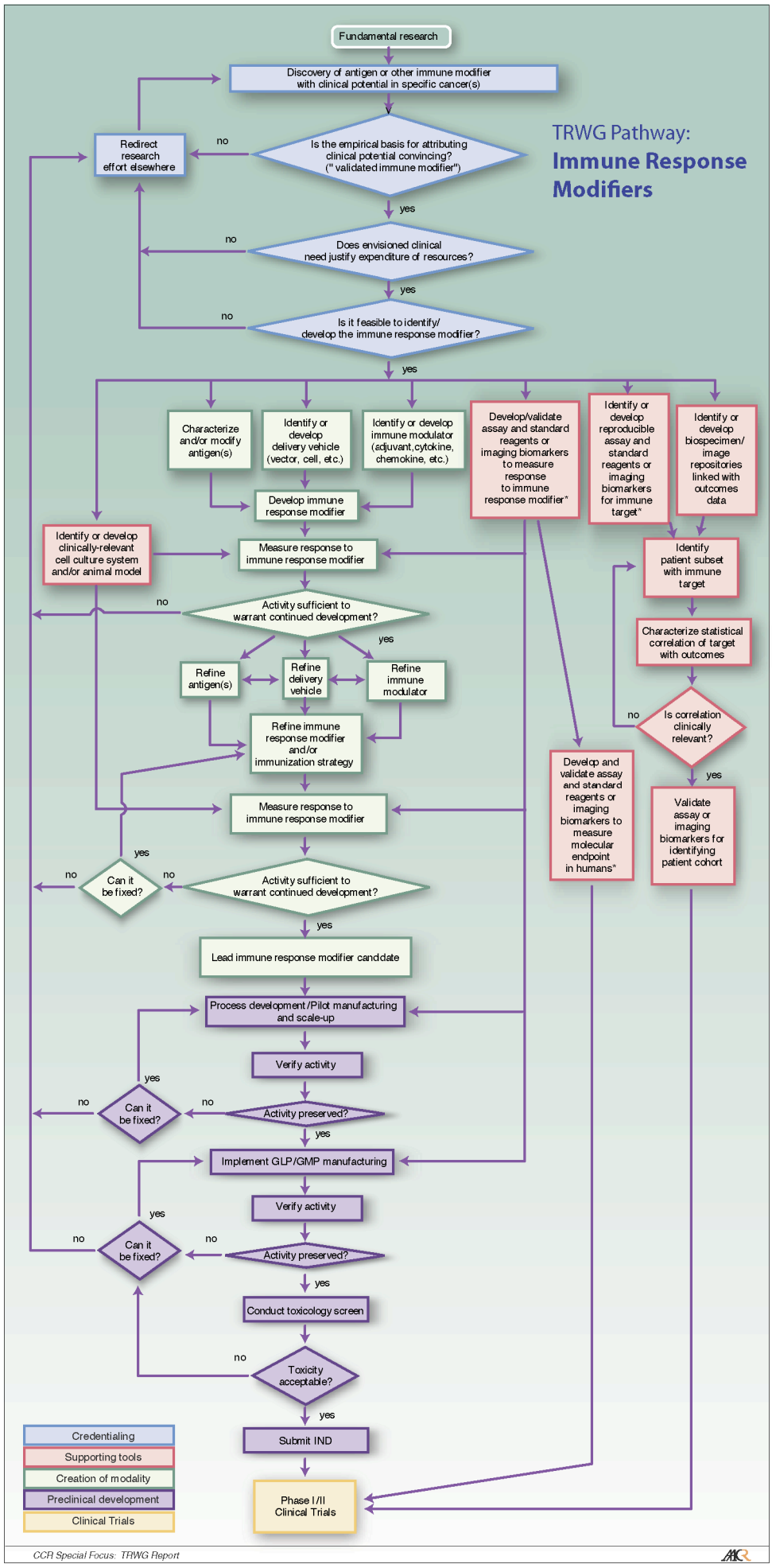
TRWG Pathway:
Immune Response Modifiers
Fundamental research
Discovery of antigen or other immune modifier with clinical potential in specific cancer(s)
Is the empirical basis for attributing clinical potential convincing? ("validated immune modifier")
Redirect research effort elsewhere
Does envisioned clinical need justify expenditure of resources?
Is it feasible to identify/ develop the immune response modifier?
Characterize and/or modify antigen(s)
Identify or develop delivery vehicle (vector, cell, etc.)
Identify or develop immune modulator (adjuvant, cytokine, chemokine, etc.)
Develop immune response modifier
Develop/validate assay and standard reagents or imaging biomarkers to measure response to immune response modifier*
Identify or develop reproducible assay and standard reagents or imaging biomarkers for immune target*
Identify or develop biospecimen/ image repositories linked with outcomes data
Identify or develop clinically-relevant cell culture system and/or animal model
Measure response to immune response modifier
Activity sufficient to warrant continued development?
Refine antigen(s)
Refine delivery vehicle
Refine immune modulator
Refine immune response modifier and/or immunization strategy
Measure response to immune response modifier
Can it be fixed?
Activity sufficient to warrant continued development?
Lead immune response modifier candidate
Process development/Pilot manufacturing and scale-up
Verify activity
Activity preserved?
Can it be fixed?
Implement GLP/GMP manufacturing
Verify activity
Activity preserved?
Can it be fixed?
Conduct toxicology screen
Toxicity acceptable?
Submit IND
Phase I/II Clinical Trials
Identify patient subset with immune target
Characterize statistical correlation of target with outcomes
Is correlation clinically relevant?
Develop and validate assay and standard reagents or imaging biomarkers to measure molecular endpoint in humans*
Validate assay or imaging biomarkers for identifying patient cohort
yes
no
Credentialing
Supporting tools
Creation of modality
Preclinical development
Clinical Trials