Clinical Imaging Steering Committee 2020 Strategic Priorities

1) Innovative clinical trials that incorporate imaging as an integral <u>biomarker</u>. Prioritization will be given to trials that use imaging as:

- a) A tool to select, stratify, and monitor response to precision medicine-based therapies, including immunotherapies (immune checkpoint blockades and T-cell based therapies)
- b) A predictive biomarker for side effects/toxicity profiling
- c) A tool to differentiate response from pseudo-progression or true tumor progression
- d) an early biomarker of response and surrogate for established endpoints
- e) Imaging as a tool to assess biodistribution of a targeted agent/companion diagnostic

2) Explore methods to improve and standardize qualitative and quantitative imaging research approaches. Areas of improvement include:

- a) Defining/standardizing MRI and/or PET imaging metrics in measuring therapeutic outcome of novel agent combinations
- b) Improving repeatability/reproducibility of imaging findings
- c) Optimization of imaging acquisition techniques and post-processing
- 3) Develop clinical trials that employ imaging to inform <u>cancer management</u>. Examples of trials include:
 - a) Trials that employ imaging as a means for cancer detection and characterization.
 - b) Trials that employ imaging as a surveillance technique to identify cancer recurrence or to assess the phenotypic transformation of lesions
 - c) Trials that employ imaging to guide response adaptive trials
 - d) Trials to alter or adapt patient management can be exploratory or definitive, the latter of which could include a comparator arm not using imaging to inform/adapt therapy.
 Collection of data on quality of life, resource utilization, quantitative imaging and

outcomes is encouraged as a trial component to provide meaningful patient-centered and societal outcomes

- 4) Assess imaging response criteria and promotion of imaging endpoints beyond RECIST, investigating if imaging during/after completion of therapy can serve as surrogate marker for ultimate patient outcome e.g., PFS, OS)
 - a) Redefine RANO (2.0)
 - b) Define response evaluation in bone
 - c) Assess volumetric based tumor burden quantitation
 - d) Test automated methods that are accurate, precise, and convenient in the clinical workflow
- 5) Assess/evaluate molecular mechanism(s) for quantitative functional imaging
 - a) Test improved physiologic (functional and molecular) imaging methods
 - i) Focus on metabolomic, perfusion and diffusion techniques
 - b) Seek the biological basis of imaging phenotypes with imaging-pathology correlations
 - i) Genomic correlates
 - ii) Proteomic correlates
 - iii) Metabolomic correlates
- 6) Strategies for collecting, analyzing, and standardizing Big Data and Radiomics features
- 7) Strategies for lowering radiation dose from imaging studies in clinical trials