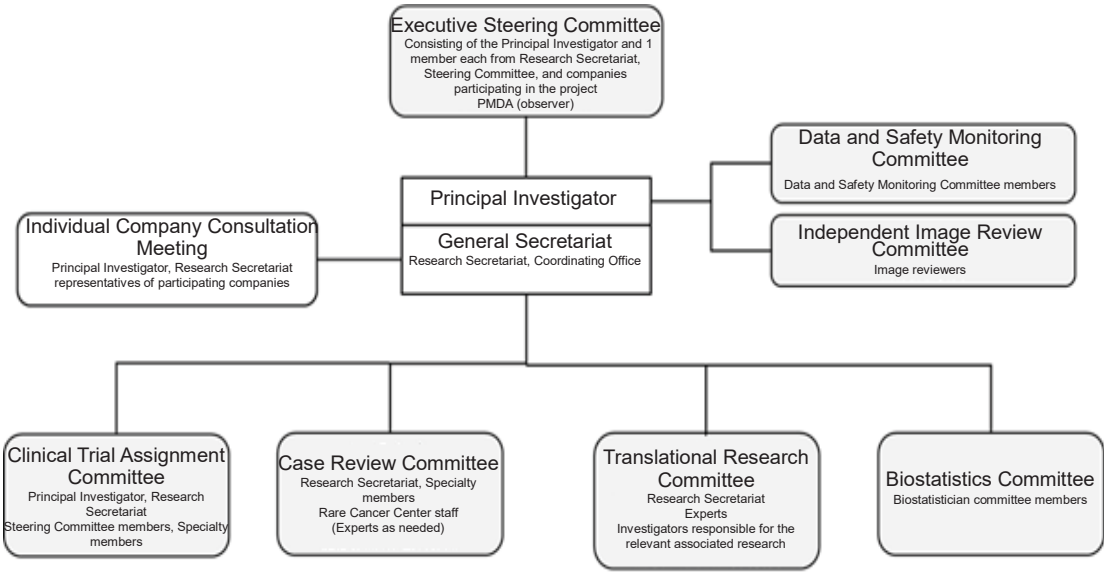
Supplementary material
(MASTER KEY Project: Powering Clinical Development for Rare Cancers through a Platform Trial)

Figure S1. Project organization and individual committee roles



Role of each committee/meeting

EXECUTIVE STEERING COMMITTEE

Receives overall progress report and budget management report on the MASTER KEY Project from the Principal Investigator and Research Coordinating Members, discusses and makes the budget for the next fiscal year, and makes a decision on the examination items submitted by individual committees. The committee members consist of the Principal Investigator and a member each from the Research Secretariat, Steering Committee, and companies participating in the project.

CLINICAL TRIAL ASSIGNMENT COMMITTEE

Selects and prioritizes clinical trials within the MASTER KEY Project. In addition, will give advice in the biomarker testing, and reviews the significance of biomarkers and corresponding study drugs. The committee consists of the members from Research Secretariat and members from the clinical departments, and experts in the field of molecular oncology from the research institute. Investigators at newly added participating sites will participate in the committee.

CASE REVIEW COMMITTEE

Reviews biomarker profiles of patients enrolled in the registry study to determine patients' eligibility for a clinical trial. Also determines appropriate actions to be taken in case a problem occurs in a patient receiving treatment. The committee consists of the clinical and research staff of the participating study sites.

TRANSLATIONAL RESEARCH COMMITTEE

Plans and determines the feasibility of associated pieces of research that utilize samples obtained from patients participating in the registry study. The committee consists of members from Research Secretariat, research experts from the research institute, and investigators responsible for the relevant associated research.

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BIOSTATISTICS COMMITTEE

Considers statistical analysis in the registry study and each clinical trial, including the study design (Bayesian, umbrella, basket etc.) and the use of registry data. Composed of the Biostatistics Division of the National Cancer Center and specialist members.

DATA AND SAFETY MONITORING COMMITTEE

Independently conducts project-wide reviews on the progress, protocol modification, efficacy, and safety etc. related to the registry study and sub-studies (excluding company-sponsored studies).

INDEPENDENT IMAGE REVIEW COMMITTEE

Conducts central image review for sub-studies (excluding company-sponsored studies) and provides recommendations regarding how imaging evaluation should be performed in individual sub-studies.

INDIVIDUAL COMPANY CONSULTATION MEETING

Company-specific consultation meetings are conducted between representatives of participating companies and the Principal Investigator/Research Secretariat/Coordinating Office to discuss about candidate study drugs, sub-study design, and/or budget