Development and commercialization of new medical technologies have great promise for improving health care. The current realities of the US health-care system dictate, however, careful attention to costs in addition to quality of care. Participants in the commercialization process for new medical devices—payers, providers, and manufacturers—express various concerns about how well the process currently functions. Payers and providers, for example, often find that evaluating the benefits and risks of new devices takes substantial resources and that available clinical information is inadequate to make informed coverage, medical necessity, and payment decisions. Manufacturers are concerned, for example, that difficulties and delays of payers and providers in evaluating new devices for coverage impede market acceptance of medically valuable technologies and thereby undermine incentives to innovate.

The purpose of the project is twofold. First, we seek to understand current processes of managed care organizations for making coverage, medical necessity, and payment decisions, and how device developers and manufacturers prepare for and participate in these processes. Second, we seek ways to improve the processes by which new medical technologies are developed, evaluated, and adopted or rejected for coverage. It is expected that manufacturers, the managed care industry, and consumers could all benefit from this effort.
The project involves in-depth interviewing of decision makers at several managed care organizations in California and at several US companies that develop and manufacture medical devices. The preliminary conclusions of the study will be presented and discussed at a roundtable meeting of key decision makers organized by RAND. The final product will be a public report by RAND summarizing the project, key findings in light of the roundtable discussion, and recommendations for further action.

The project is being conducted by RAND Health in cooperation with the Health Industry Manufacturers Association (HIMA). RAND is a private, not-for-profit institution based in Santa Monica, California that helps improve policy through research and analysis. HIMA is a trade association based in Washington D.C. that represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. The project is sponsored by the Goldstrike Partnership, a program of the California Trade and Commerce Agency’s Office of Strategic Technology.