ANSI Committee on Education

Standardization Case Studies

ACCOMPANYING QUESTION AND ANSWER WORKSHEET

As appropriate, please suggest recommended study, test or quiz questions / answers to accompany the case study proposed above.

Proposed Question	Discuss the advantages versus the risks for countries with lax regulations for conducting clinical trials that involve human subjects.
Proposed Answer	Discussion should address availability of devices/medicines to patients, potential for economic advantage, safety risks, and device/medicine performance/effectiveness.

Proposed Question	How does ISO 14155 as an international standard confront the ethical issues of medical tourism?
Proposed Answer	Explanation should describe how the standard can ease trade restrictions, provide governments with a technical base for health, safety and environmental legislation and conformity assessment, and safeguard consumers, at minimum.

Proposed Question	The United Kingdom believes that regulators, not manufacturers, should define regulations for conducting device clinical trials. German physicians believe that regulations should not take power from the physician investigators. How does the expertise of these two groups compare to manufacturers who participate is setting these trial standards in the US?
Proposed Answer	Answering this question may take research as well as thought. Physician investigators best understand the medical aspects of the trial. Regulators may best look out for the welfare of the subjects and the ultimate ability to translate findings into acceptable data. Manufacturers will understand the requirements for producing safe, high quality devices. Discussion should include ethical and commercial implications of each groups strengths.