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New tool to speed cancer therapy approval available

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Although cancer remains a leading cause of death in America, it can take up to 12 years to bring a new anti-cancer agent before the FDA and the success rate for approval is only five to 10 percent. That means many research hours and dollars are wasted chasing avenues that will not bring fruit.

The National Cancer Institute's Translational Research Working Group (TRWG) developed a set of tools that it believes will improve that process. The tools, known as
"Pathways to Clinical Goals" are published in the September 15 issue of *Clinical Cancer Research*, a journal of the American Association for Cancer Research.

"The NCI supports a great deal of excellent translational research, but inefficiencies arising from a lack of communication and coordinated effort prevent many promising leads from reaching clinical trials and eventual approval," said Lynn Matrisian, Ph.D, a special assistant in the Office of the Director, NCI. Matrisian co-chaired the TRWG, which was formed in 2005 with the goal of accelerating the pace of translational cancer research. Publication of the Pathways is expected to be a major step forward in this process.

There are six Pathways that address the following categories: anti-cancer agents (drugs or biologics), biospecimen-based assessment methods, immune response modifiers, image-based assessment modalities, intervention devices, and lifestyle alterations.

Each pathway is a flowchart with a series of steps intended to clarify and streamline the translational research process. For example, in the anti-cancer agent pathway, researchers are encouraged at the outset to address the following three questions:

-- Is the empirical basis for attributing clinical potential (alone and/or in combination) convincing?
-- Does the envisioned clinical need justify expenditure of resources?
-- Is it feasible to identify/develop an agent against this target?

Matrisian and her colleagues hope that the TRWG pathways will be widely used and that they will make the early translational research process more efficient.

"The NCI funds many important research projects, and we hope these pathways will help in placing each research opportunity in the broader context of tangible cancer detection, diagnosis, prevention, and treatment strategies. We believe the NCI 's experience will be an important resource for other groups advancing translational research as well," said Matrisian.

Source: American Association for Cancer Research