

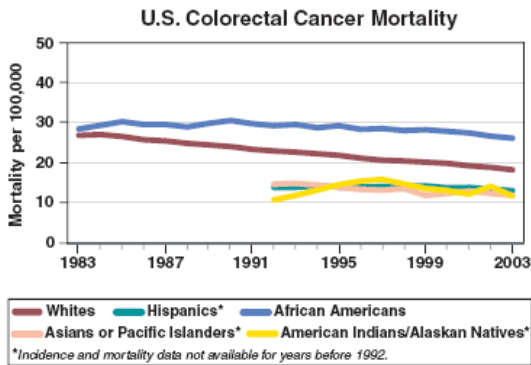
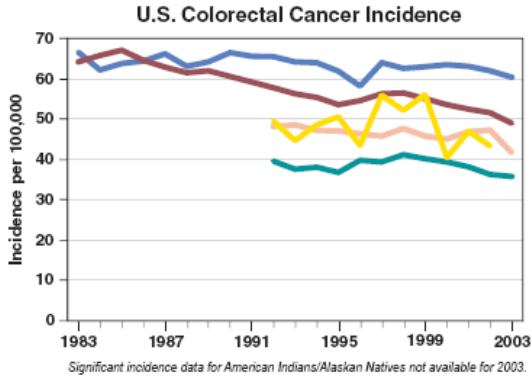


**Ockham Technical Synopsis** is a recurring series prepared for internal staff and consultants of Ockham Development Group Inc. (Ockham). Highlighting current and emerging issues and challenges in clinical research, these publications are intended to disseminate intelligence captured during the execution of key clinical trials and are therefore updated on a continuous basis.

**COLORECTAL CANCER  
DISEASE INCIDENCE, SITE AND PATIENT  
RECRUITMENT ASSESSMENT**

**INCIDENCE AND MORTALITY RATE TRENDS**

Colorectal cancer is the third most common cancer and the third leading cause of cancer-related mortality in the United States. Over the past decade, colorectal cancer incidence and mortality rates have modestly decreased or remained level.



Until age 50, men and women have similar incidence and mortality rates; after age 50, men are more vulnerable.

There are striking differences between racial and ethnic groups in both incidence and mortality. Mortality rates for Hispanics, Asians or Pacific Islanders, and American Indians/Alaskan Natives are lower than those for Whites or African-Americans.

It is estimated that approximately \$8.4 billion<sup>1</sup> is spent in the United States each year on treatment of colorectal cancer.

**PATIENT RECRUITMENT ASSESSMENT**

Over the last five years the number and diversity of colorectal cancer trials has increased substantially. Current estimates of enrollment rates vary considerable based on cancer staging in previous therapy.

Below is a summary of enrollment rates for a selection of recent colorectal cancer studies.

Study Number	Number of Patients	Number of Sites	Enrollment Period (months)	Enrollment Rate (pts/site/month)
1	923	163	18-29	~0.23
2	329	56	10	~0.58
3	110	27	20-29	~0.14
4	105	4	18	~1.45
5	183	32	19	~.301

Ockham currently estimates enrollment rates in the range of 0.25 to 0.4 (depending on stage, previous therapy and inclusion/exclusion).

<sup>1</sup> Source for incidence and mortality data: Surveillance, Epidemiology, and End Results (SEER) Program and the National Center for Health Statistics. Additional statistics and charts are available at <http://seer.cancer.gov/>.