From: Hommel, Carolyn - OC
Sent: Tuesday, April 20, 2004 9:44 AM
To: [purged]
Subject: RE: Clinical Trials Question

Dear Mr. [purged]:

The Food and Drug Administration does not have any information about the costs associated with the various types of medical imaging used in clinical trials, nor, for that matter, the costs associated with any other health care procedure or product. I checked with our Center for Devices and Radiological Health, in case they were aware of any organizations that might have such information, and they suggested that you might try contacting the American College of Radiology Imaging Network, or the American College of Radiology.

You might also try contacting the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration); their website is http://www.cms.dhhs.gov. CMS sets the fees for medical services that are reimbursed by the Medicare program, and perhaps they would have some publicly available information about the costs associated with various diagnostic procedures (including medical imaging techniques).

I hope this is helpful to you.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Phone: 301/827-3340
Fax: 301/827-1169

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [purged]
Sent: Monday, April 05, 2004 2:00 AM
To: Carolyn.Hommel@OC.FDA.GOV
Subject: RE: Clinical Trials Question

Thanks Carolyn. Your numbers were helpful.

I have another question that I wonder if you or someone else could help me with. I'm hoping to gain a better understanding of the image (CT, MRI, PET, etc) management costs incurred for clinical trials that use images as an endpoint or surrogate endpoint. More specifically, what is a rough dollar figure or percentage of total trial costs for functions such as:
- transporting images from a site to a central archive.
- archival costs
- creation of duplicate images in case of loss of original

If there are any resources you could point me to, I'd truly appreciate it.

Thanks in advance,

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