

Plus ca allez, plus ce la
meme chose

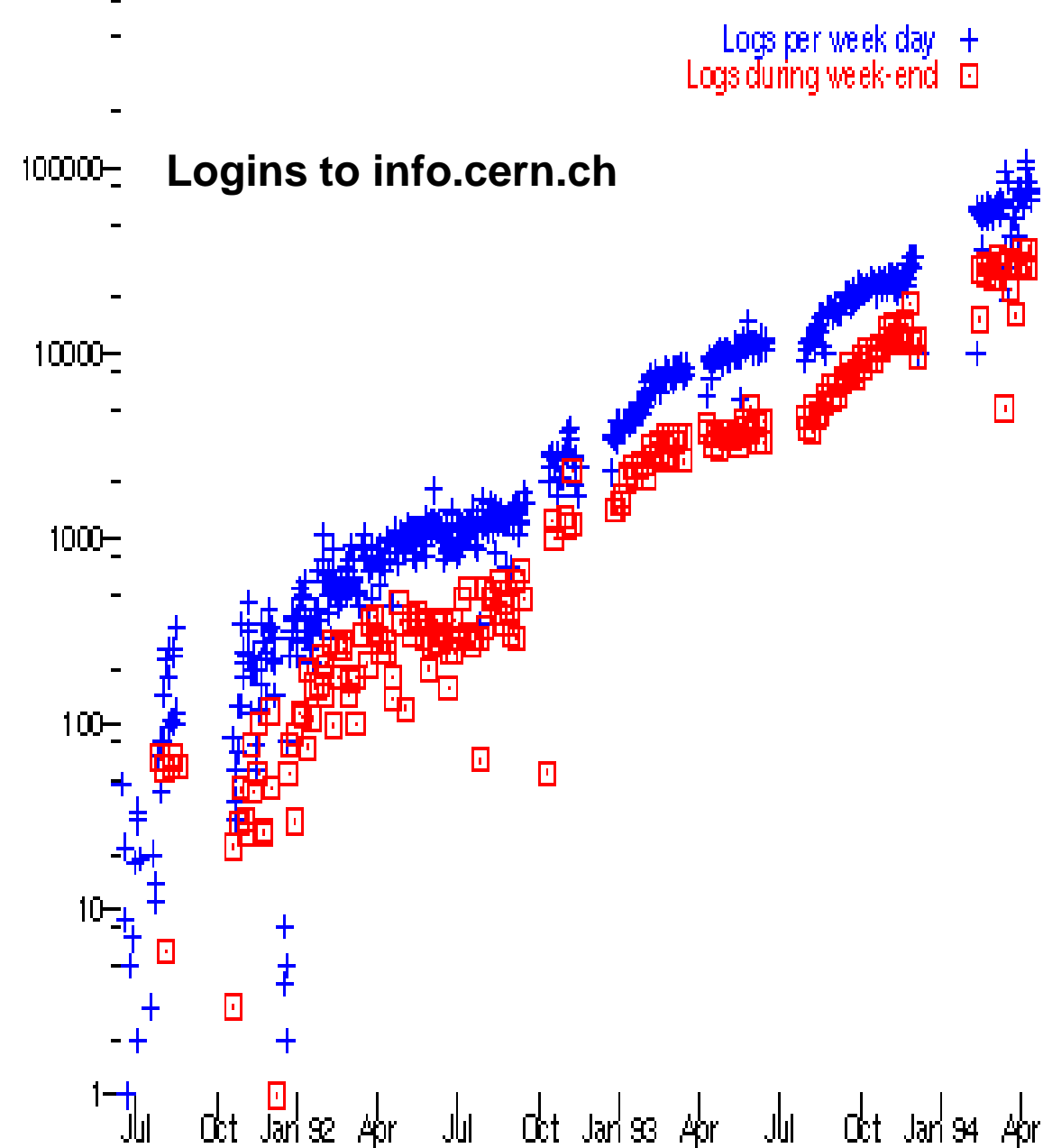
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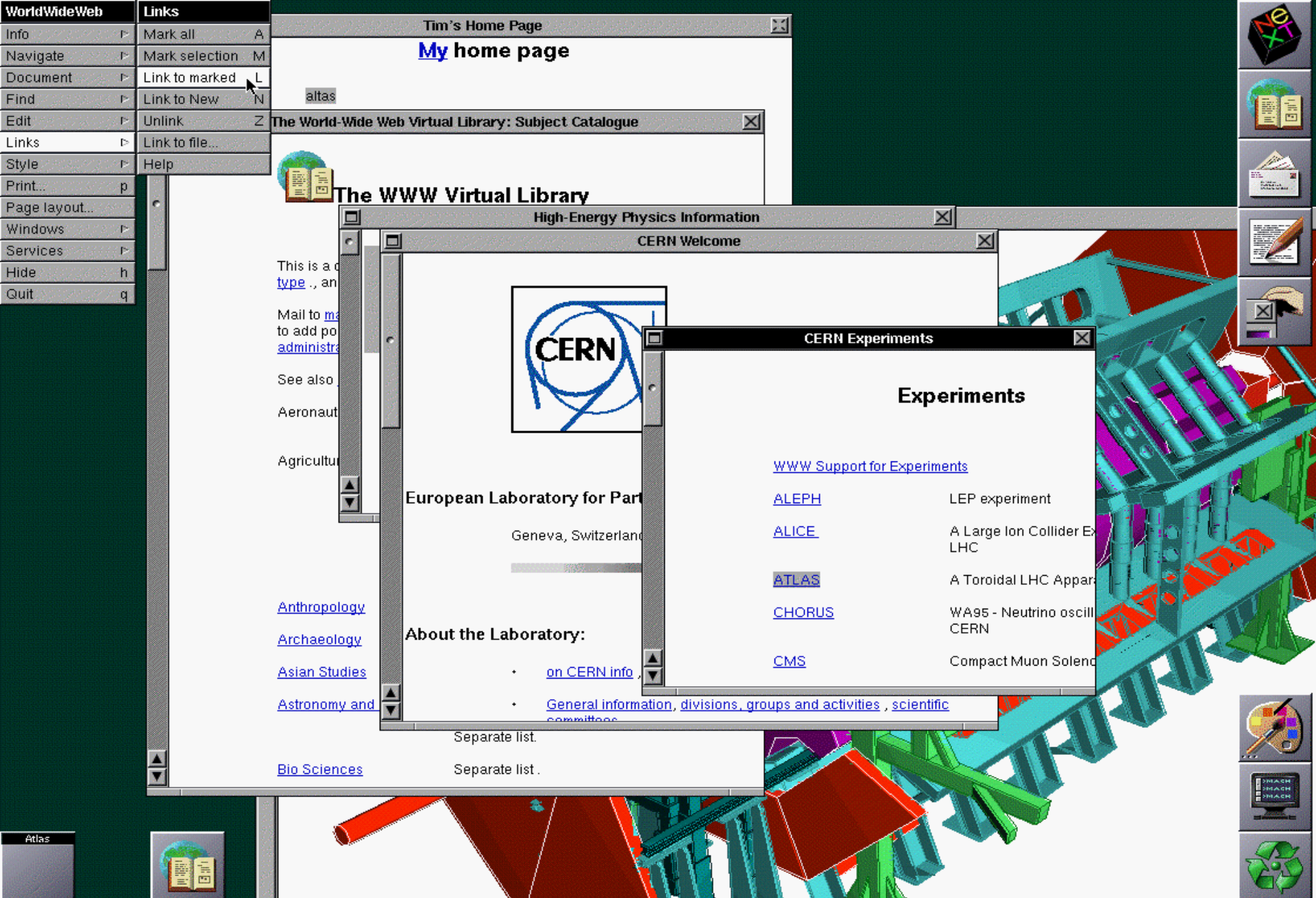
Mobile may be cool – but is it *different*?

Arthur Brandwood

amdahl







- Do It by Design: An Introduction to Human Factors in Medical Devices
- Human Factors in Medical Device Design (1997)
- Guidance for Industry: Software Requirements for Medical Devices
- Applying Human Factors Principles to Medical Device Design (Update)
- Guidance for Industry: Medical Device Labeling (Update)
- Guidance for Industry: Medical Device Life Cycle Processes (Update)
- [510(k) Premarket Notification Submissions]

DO IT BY DESIGN

An Introduction to Human Factors in Medical Devices

By *Dick Sawyer*
Office of Health and Industry Programs

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U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health

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Your MRI is calling: FDA approves first medical iPhone app

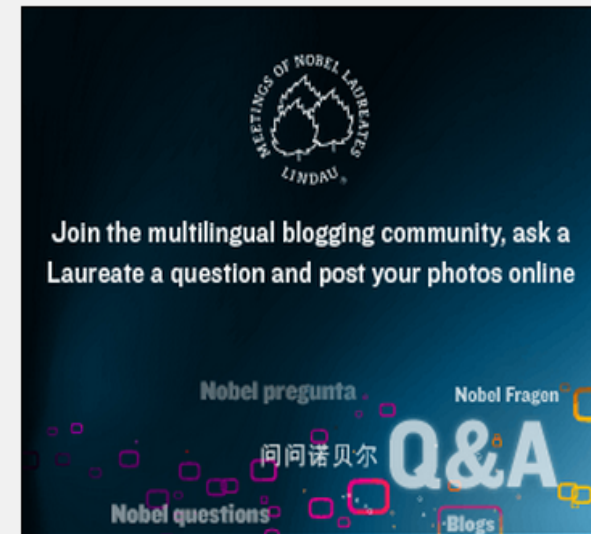
By Katherine Harmon | Feb 7, 2011 03:00 PM | 2

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A medical smart phone app that allows doctors to view and assess medical images has been approved by the U.S. Food and Drug Administration for the first time. The program, called Mobile MIM, runs CT, PET

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Contains Nonbinding Recommendations
Draft – Not for Implementation

Draft Guidance for Industry and Food and Drug Administration Staff

Mobile Medical Applications

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: July 21, 2011

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul.Patel@fda.hhs.gov. For questions regarding this document concerning devices regulated by CBER, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 301-827-1800.



U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

FDA will use *Enforcement Discretion* – so what's covered?

HOT

- **Apps which control another device**
- **Mobile device with accessories – e.g. sensors**
- **Apps with algorithms to process patient data.**
- **What about Apps as accessories to regulated devices?**

NOT

- **Medical eBooks**
- **General health info websites**
- **General wellness/health apps**
- **Generic use apps not specifically medical**
- **Health Records systems**
- **Medical Device Data Systems**

And the FDA hasn't changed either: Design Control is for NOW

- **Ensures product development meets requirements**
 - **Submissions will be truthful and accurate**
 - **Regulatory and Product Development Process are the SAME**
- ...Do it all ONCE**
- **It will be audited later**

