Safeguarding public health

eWorking at the MHRA

The impact of the Sentinel programme

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Take away Messages

- MHRA has made a significant investment in eWorking
- “Electronic CTD” or NEES applications now making up to 70-80% of all applications, no paper copies required
- Less than 15 full eCTD application received since August ’05
- Collaborative eCTD pilot set up with applicants
- Several eCTDs in preparation
- Use of MHRA Portal is mandatory for eCTDs
- New targets agreed with industry to facilitate transition from paper to full eCTD applications

Topics to be covered

- Sentinel Programme Overview
- MHRA Portal
- Sentinel Case Folder
- Electronic Submissions
- eCTD Pilot Scheme
- Moving Forward
- New eWorking Targets

Sentinel Programme Overview

Why was Information Strategy Required?

- Business applications, PLUS, ADROIT, BLIS were fairly old end to end thick client systems
- Information held in business silos
- Difficult to get critical cross agency BI information
- Front end architecture was obsolete
- Dictionaries contained duplicate information
- Remote working not possible
- eCTD applications not catered for in business processes

Sentinel Programme Summary

- *Oracle HR Jan ‘04*
- *Oracle Finance April ‘04*
- *Clinical Trials August ‘04*
- *Export Certificates January ‘05*
- *Product Licensing August ‘05*
- *Manufacturing / Inspection Licensing October ’05*
- *Portal / RamaXL November/December ‘05*
- *Pharmacovigilance May 2006*

Sentinel Impact

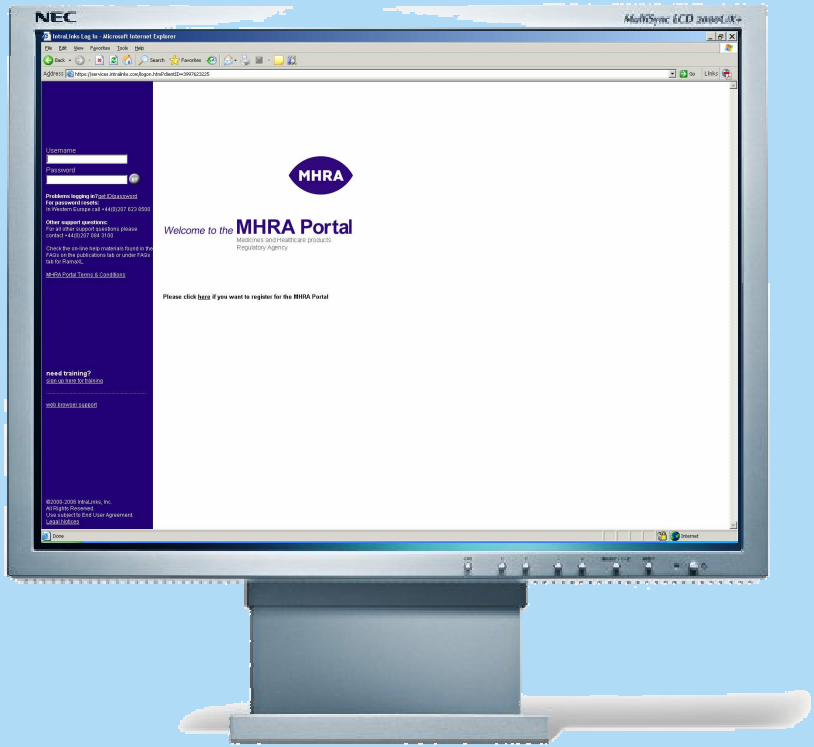
- Major change in working practices for MHRA
- Over 28 million Gold file pages have been scanned
- All current business systems have been replaced
- Secure verification of identity through portal
- Electronic records are the master
- Massive reduction in paper storage and handling
- Improved quality / consistency in assessment and response to queries
- All IT support activities grouped together and outsourced

Sentinel Consequential Changes – Business Re-alignment

- Assessment teams regrouped into therapeutic areas
- All data entry activities grouped together in new IPU within IMD
- Assessment teams deal with full product life cycle: initials, variations, renewals
- Centralised Regulatory Information Service (RIS) to handle majority of applicant queries

MHRA Portal

MHRA Portal for secure electronic working with clients



Benefits of Portal to Industry

- All applications/communications are electronic
- Secure 24x7x365 e-gateway into MHRA for applications and communications
- Improved speed of communications
- On-line data validation using Sentinel web services
- No archive paper copies are required
- Service is free for up to 5 users
- The Portal provides a gateway to the RamaXL added value service (Rama successor)
- Uses standard PC hardware and Adobe 7.05 Reader

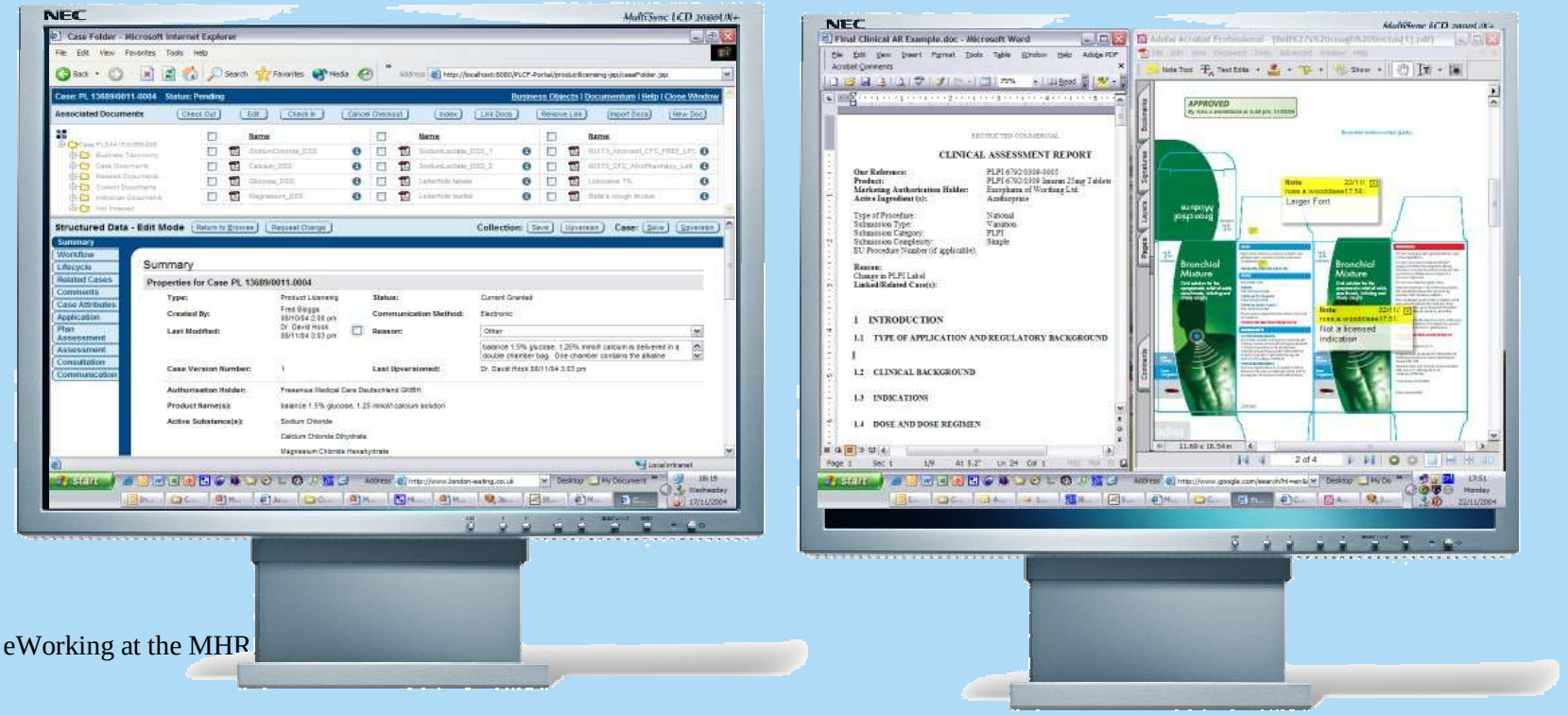
Sentinel Case Folder

- For all **internal** facing activities:

  - Review tool for assessment of electronic applications
  - Workflow management
  - Related licence and document comparison
  - Consultation activities with CHM or CHMP
  - Communications
  - Determination process

Sentinel Case Folders

Each major business area has a specific Case Folder to manage their work



Electronic Submissions

NEES Applications

- PDFs in CTD format accepted
- No additional paper copies required
- Any paper submitted is scanned prior to use
- 70-80% applications in “electronic CTD” format
- Detailed guidance given in Special Mail 5 and FAQs
- Interim measure only – note FDA have end-date of December 2007

MHRA eCTD submission – the “Ideal”

- MA application form from MHRA Portal completed via Web Services
- **PLUS**
- M1 according to EU 1.1 specification (update to 1.2.1 pending) and M2 to M5 as per ICH 3.2 specification
- **PLUS**
- SmPC as separate Word file using MHRA template

Advantages of MHRA eCTD Format

- Portal MA form creates Case Folder for structured data
- eCTD xml enables auto upload of documents into Documentum
- Speeds up data entry processes
- Reduces data errors

Current eCTD Issues

- Impact of changes to specifications and MA application form during both application and product life cycles
- No concept of regulatory view in eCTD specification
- Product life cycle management, use of operations
- eCTD granularity
- Interoperability of eCTDs from different tools (Pilot Scheme)
- EU processes not yet re-engineered for eCTDs
- Very few eCTDs received

MHRA eCTD Pilot Scheme

eCTD Pilot Production Scheme I

- Aims to test outputs from applicants eCTD tools in a production situation
- Will help to formulate specific eCTD/Portal guidance
- MHRA leading a TIGes eGuidance Topic Group to prepare harmonised advice on eCTD applications
- Collaborative approach is best way forward – we are all learning!

Issues found so far ……

- Absence of Portal Form
- PDF optimiser in tools can remove XML from Portal Form
- Special characters can cause problems
- Use of TOC not required
- New place holders – inclusion in folders that do not have a leaf element
- More to come……..

eCTD Pilot Findings

- One eCTD per strength of product?
- Use of document operations: NEW for all first time initial and variation eCTD applications. REPLACE for updating eCTD via RFI or new variation application
- Updating of eCTD as specifications change?

Moving forward

- MHRA using bespoke Case Folder to review eCTDs
- EURS tool to be provided by IABG
- EMEA setting up central repository for CP initially and then possibly DCP/MR applications
- MHRA eCTD pilot process in place
- Testing outputs from commonly used eCTD tools
- MHRA e-working conferences, next one end of June
- Fee increases for non-eCTD applications
- New targets for e-working agreed with industry

New eWorking Targets

- No paper applications after December 2007
- eCTD applications for new actives from April 2008
- eCTD applications for all new initial applications from Jan 2009

Thank you

And Finally

For more information on eCTD applications, including possible pilots, please contact David Wheeler or Andrea Johnson:

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Sentinel Application Architecture