



Submission
Management



Document
Management



Software
Engineering



Software
Validation



Knowledge
Portals



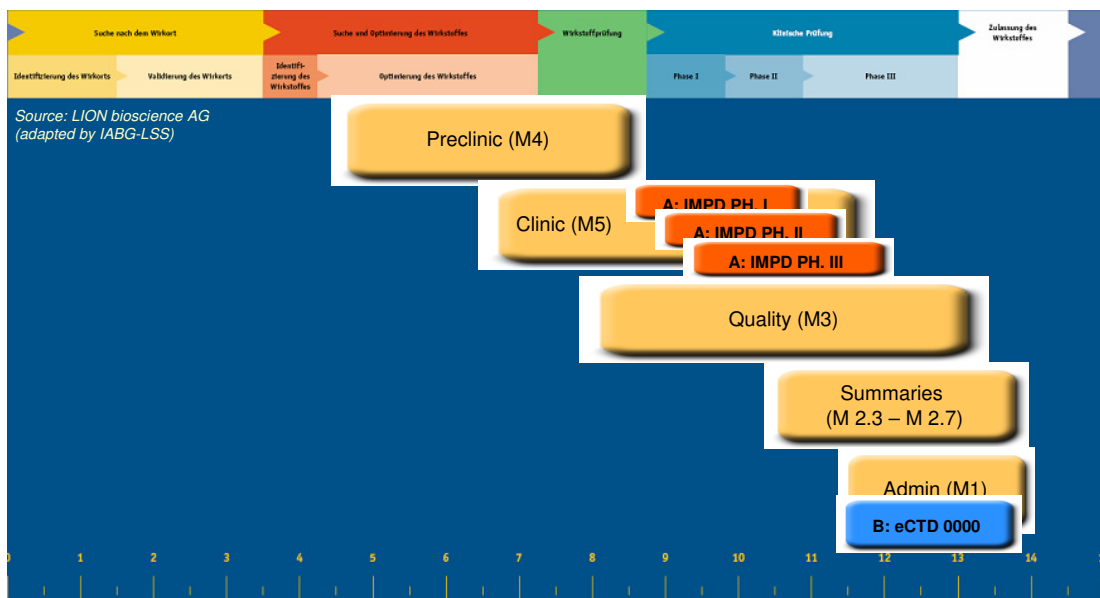
IMPD and STF - a solution for study management inside an eCTD

Thomas Staedter, PhD, IABG Life Sciences Solutions
OPENeCTD Forum, Brussels, March 28th, 2006

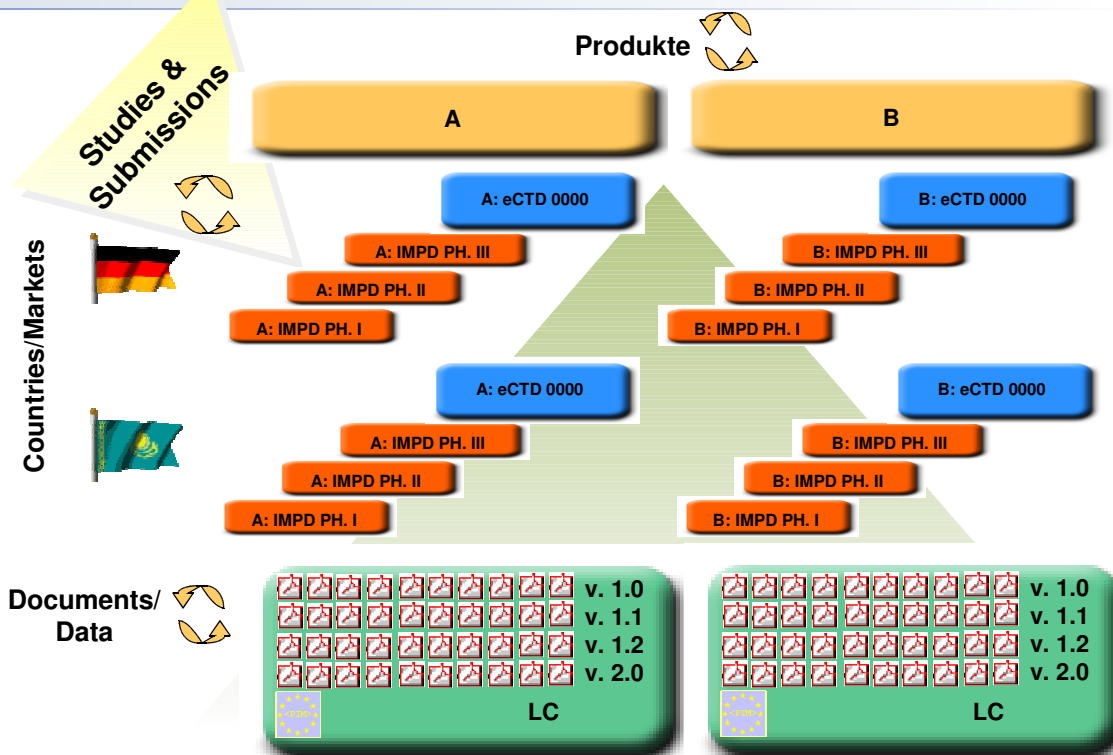
Agenda

- Managing IMPDs and eCTDs
- Associated Problem Statement
- Live Demonstration: Creating IMPDs, studies and eCTDs

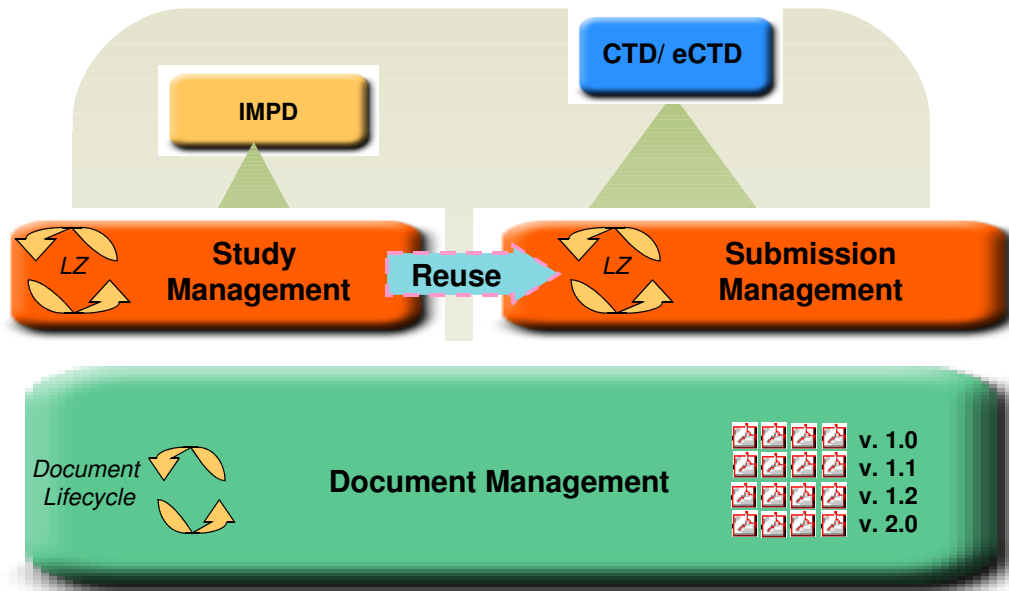
Compiling documents from an eCTD perspective



Complexity of Managing IMPDs and eCTDs

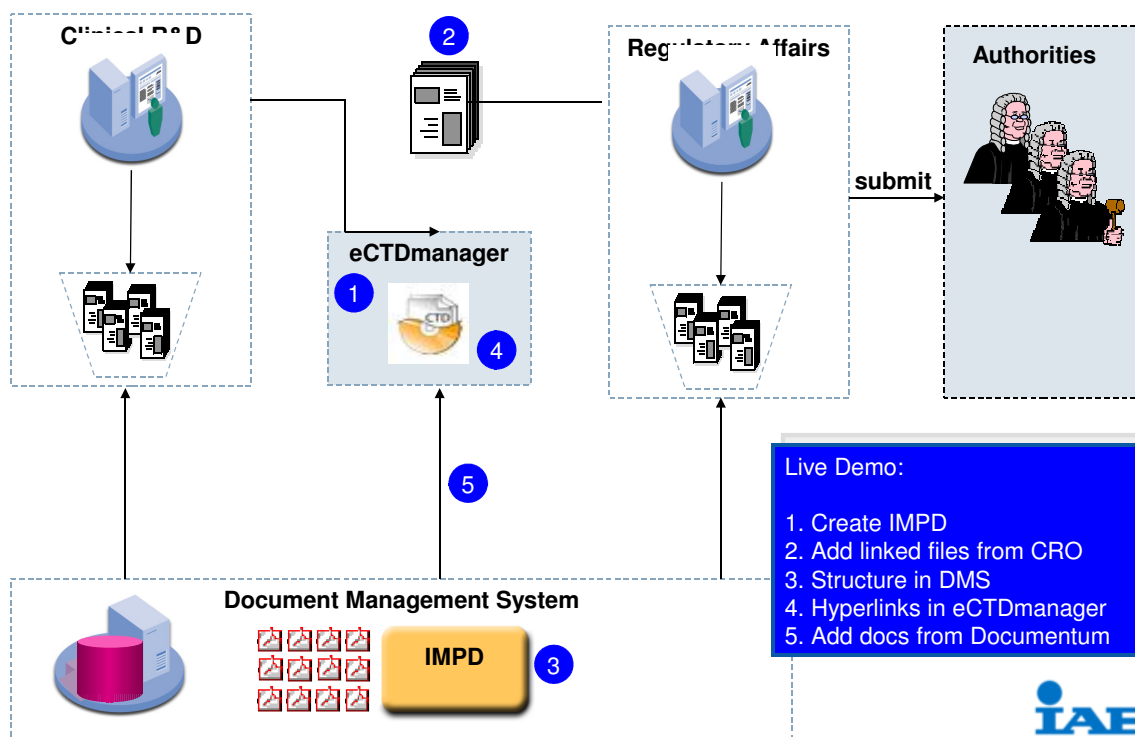


Document-, Study- and Dossier Lifecycles



5

Creating and submitting IMPDs

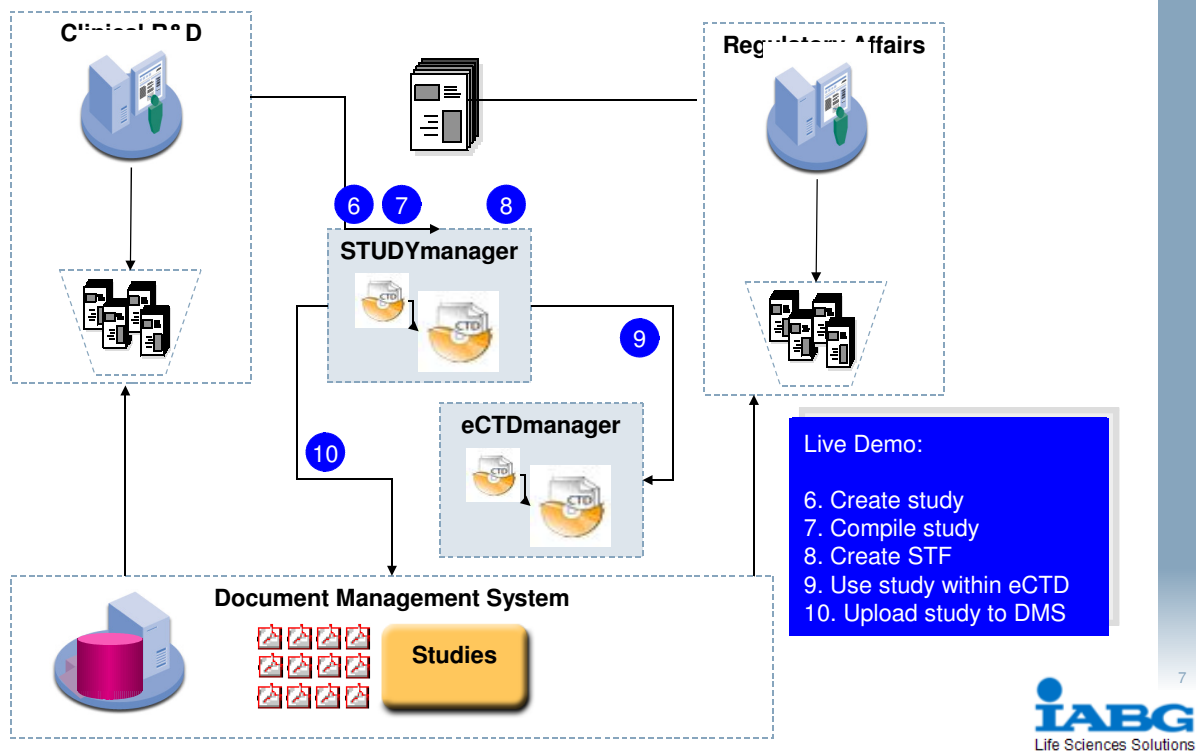


Live Demo:

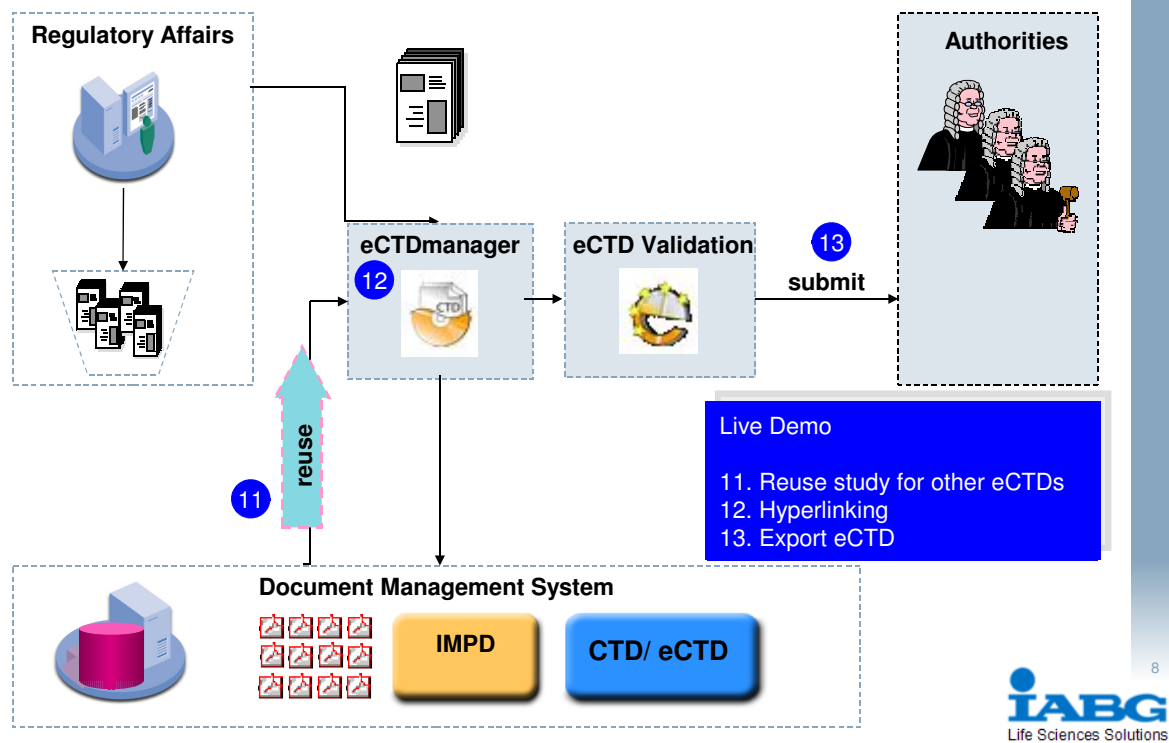
1. Create IMPD
2. Add linked files from CRO
3. Structure in DMS
4. Hyperlinks in eCTDmanager
5. Add docs from Documentum

6

Creating and compiling clinical studies (IMPD has been approved)



Creating and submitting an eCTD



Thank you
Vielen Dank
Merci beaucoup
Muchas Gracias
Tak, Tack, Takk
Doomo arigatoo

IABG Life Sciences Solutions
Einsteinstr. 30
85521 Ottobrunn
Germany

Dr. Thomas Städter
Managing Consultant

Tel.: +49-89-2351-202-22
staedter@iabg-lss.com

