



Working together, incl Industry SIEF IT tool
Krakow 5/6 March 2008





Working in SIEF & Consortia including related agreements



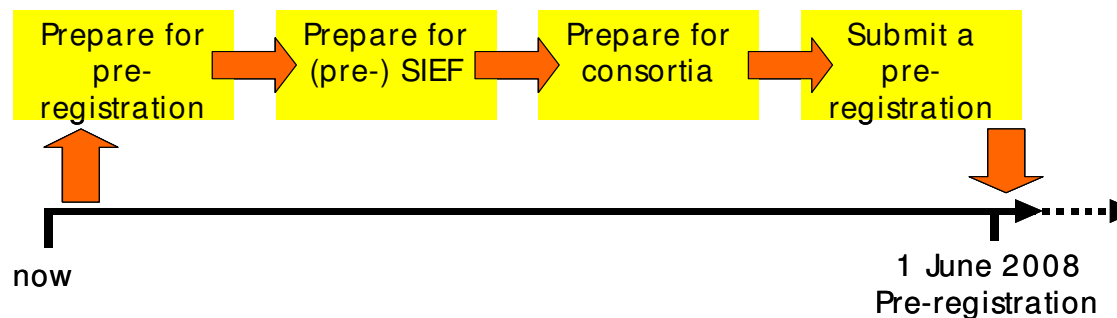
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***Senior Legal Counsellor & Governance
Officer***



Working together

- **SIEF Mandatory**
- **Consortia advised to enter in**
- **Other means of cooperation**
 - ➔ **SIEF IT Industry System**





Working together

- **First step for companies**
= Pre-registration

↓ List of contacts in each SIEF (provisionally)

↓ Various elements to take into consideration

Working together

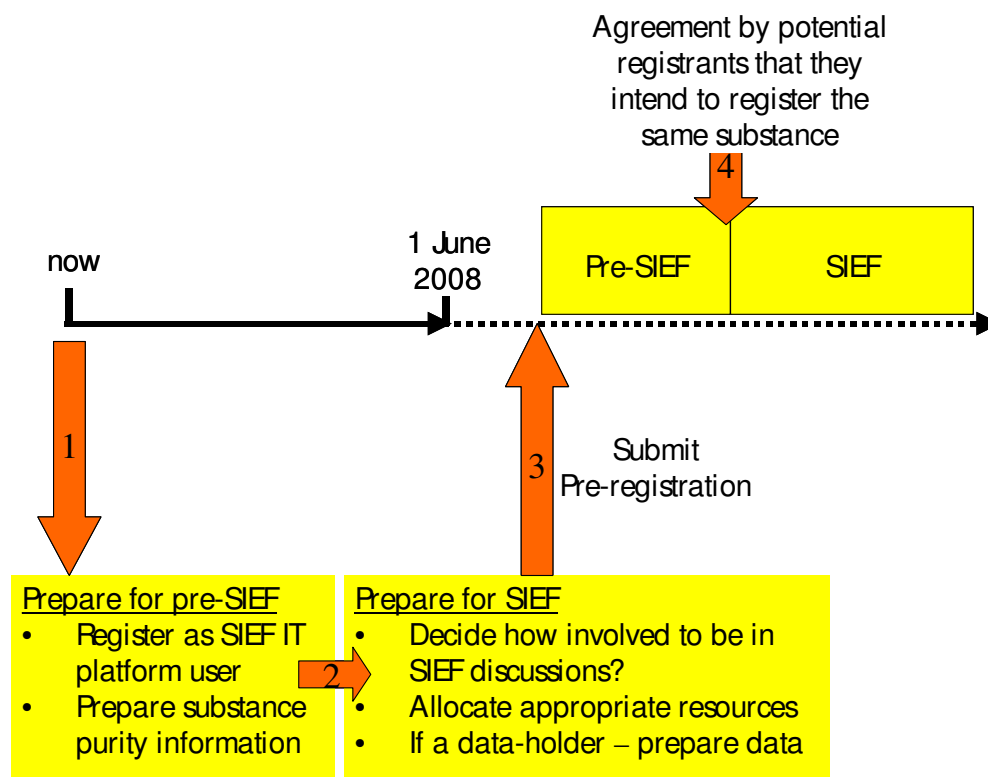


Various elements

- **Who are the others on the ECHA contact list?**
- **Practical matters**
 - **Languages**
 - **Habits of works**
 - **Number of contact lists to deal with in parallel, nearly at the same time**
 - **New comer (importers, only representatives, third party representatives, data holders...)**



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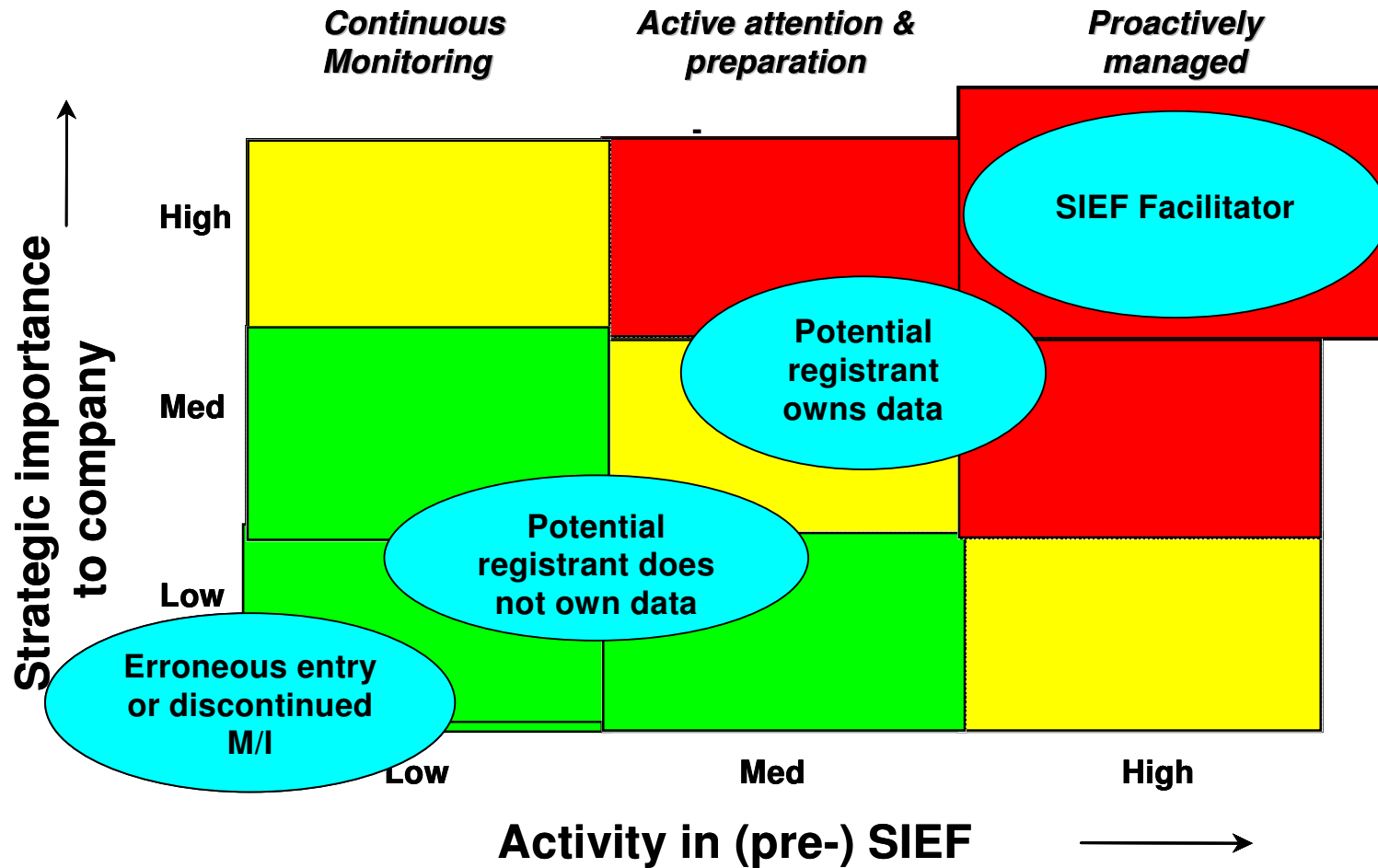


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Identify

- **What are your priorities in terms of SIEFs**
 - ↳ **Volunteers as Facilitator**
 - ↳ **If not find out if someone has volunteered**
- **Opportunities of pre-consortia discussions**

Working together





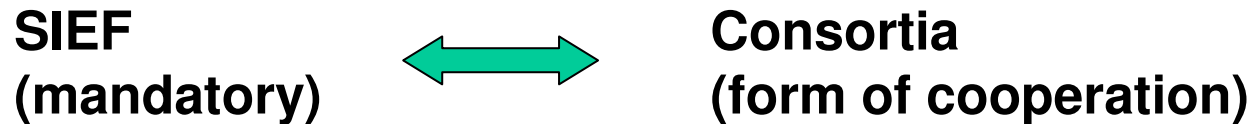
Working together

- **Already have a strategy “in house” the company on type of cooperation you are willing to adopt (may be different according to the substance and thus the SIEFs)**
 - **Lead Registrant**
 - **Facilitator**
 - **Reactive only**
 - **Dormant**

SIEF / Consortia



Working together



- **Company may always decide not to enter into consortia and simply “pay” for access data and co-operate via the SIEF for the joint submission**
- **However, it may be an “appropriate” safeguard measure to have rules adopted → still better to enter into Consortium**
- **But, different membership categories may exist**



Working together

Typical consortium activities :

- Conduct or document the identity check;
- Designation in a SIEF of the facilitator or the Lead Registrant;
- Organization of the co-operation and thus the consortium;
- Consideration of data Defining data to be shared;
- Facilitating data-sharing and coordination;
- Data valuation, data evaluation (including identification, data access and collection);
- Facilitating cross-reading between SIEFs;
- Adopting competition law compliance rules;
- Organization to preserve the CBI and data; Data ownership;
- Cost sharing
- Preparation of letter of access to data for non-consortium participants;
- Classification and labelling.

Post-SIEFs actions: e.g. joint submission of data, joint registration, and maintaining the life of the consortium even after the joint registration - jointly to follow-up the file until final registration/evaluation, including interacting with the ECHA.



Working together

Clauses of an agreement :

1. General Information :

Identity of each party

Contact details

Preamble: including a reference to the REACH Regulation and a declaration of intent to explain the overall purpose of the consortium

Scope cooperation: the substances (s) on which the parties will co-operate. It may also include the criteria chosen to agree on the identification of the substance (s)

Subject of the agreement: list of elements of co-operation or tasks on which parties have elected to work

Definitions: general reference to the definitions included in the REACH Regulation (Article 3) and additional definitions, if any

Duration Identity of a independent third party: if the parties elect to have the assistance from a law firm, service provider, sectoral or trade association to manage their consortium



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2. Membership

Membership categories: definition, rights and obligations of each category

Membership rules: admission, revocation, dismissal of members

Change in membership: late entrant / early departure

3. Data sharing

Rules on data sharing

Criteria for valuation of studies/tests reports

Cost sharing criteria

Data Ownership

Letter of access



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4. Organization

Committees: (membership, attendance, rules of functioning, quorum, voting ...)

Working language

Role of the facilitator, if any

Role of the Lead Registrant, if any

Role of third independent party, if any

5. Budget and Finances

Budget

Apportionment

Financial year

Invoicing and payment Taxes and other costs



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6. Confidentiality and right of information

Confidentiality clause

Who is entitled to access information?

Measures in place regarding the exchange of confidential and sensitive information?

Sanctions in case of breach

7. Liabilities

8. Miscellaneous

Reference to competition compliance rules

Applicable law

Dispute resolution / settlement or choice of jurisdiction

Changes to the agreement

Dissolution



Working together

- **Cefic Model Agreement Consortium**
 - Finalised for Cefic Members, National Federations
 - Available upon request to fia@cefic.be
- **Cefic competition law guidance – Do & Don't**
 - Distributed
 - Federations may decide to translate it

SIEF IT System



WHY: Chaotic situation without IT support for communication and structured processes – very limited support from the Agency

HOW: Communication tool for

- “pre-SIEF” (sameness discussions)
- data sharing, classification & labelling preparation of joint submission
- open for everybody against a (low) fee
- owned and managed by ReachLink operated and hosted by IBM

WHAT: Based on available software with additional:

- security by strict system for controlled access to system
- .- structure to facilitate SIEF work

SIEF IT system - Background



The obligation to share animal study data in SIEFs (Substance Information Exchange Fora) and Submission of a Joint Registration:

- **is industry's responsibility**
- **the European Agency (ECHA) will not be involved**
- **therefore industry has to find a solution**

IT platform giving service to all industry

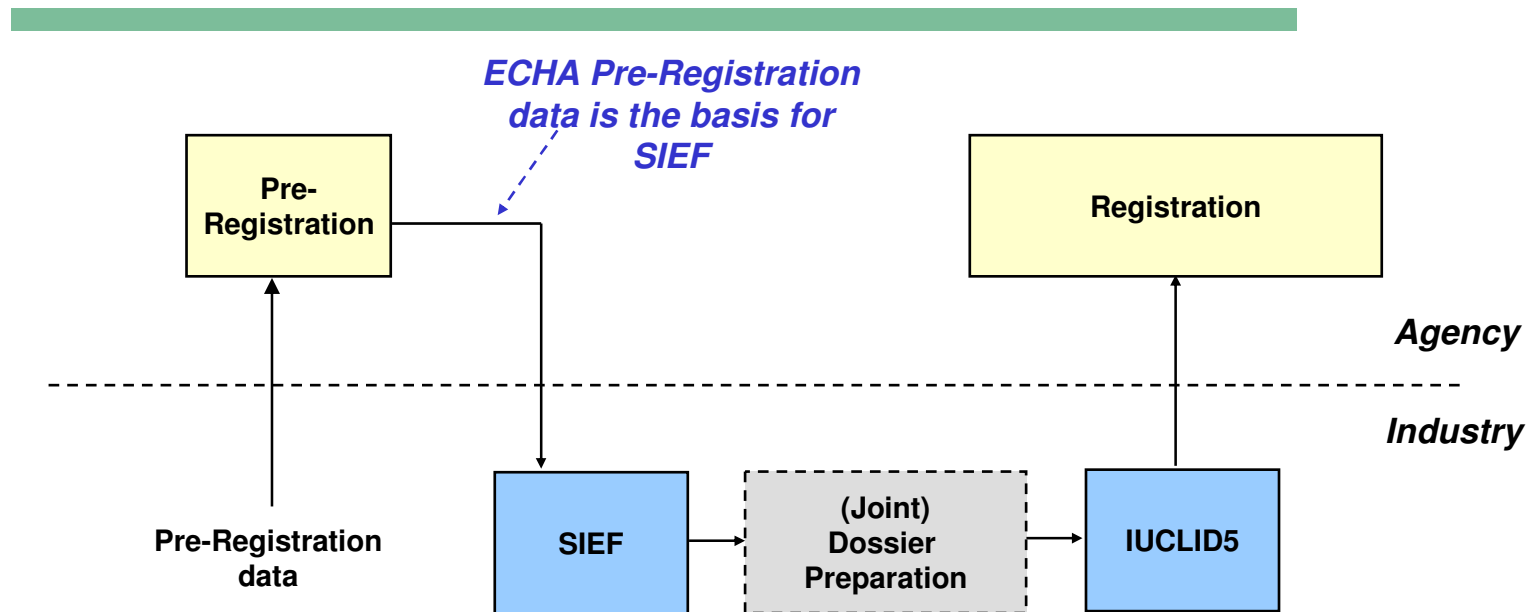
Providing for:

- **Collaboration of companies in SIEF formation & sharing of studies, identification of data gaps, cost sharing, etc.**
- **Secure communication inside and between SIEFs**

Benefits for companies of a SIEF IT platform:

- **Consistent processes and procedures**
- **No need for individual solutions (reducing complexity)**
- **Reduced investment and lower operational cost per company**

SIEF IT system project



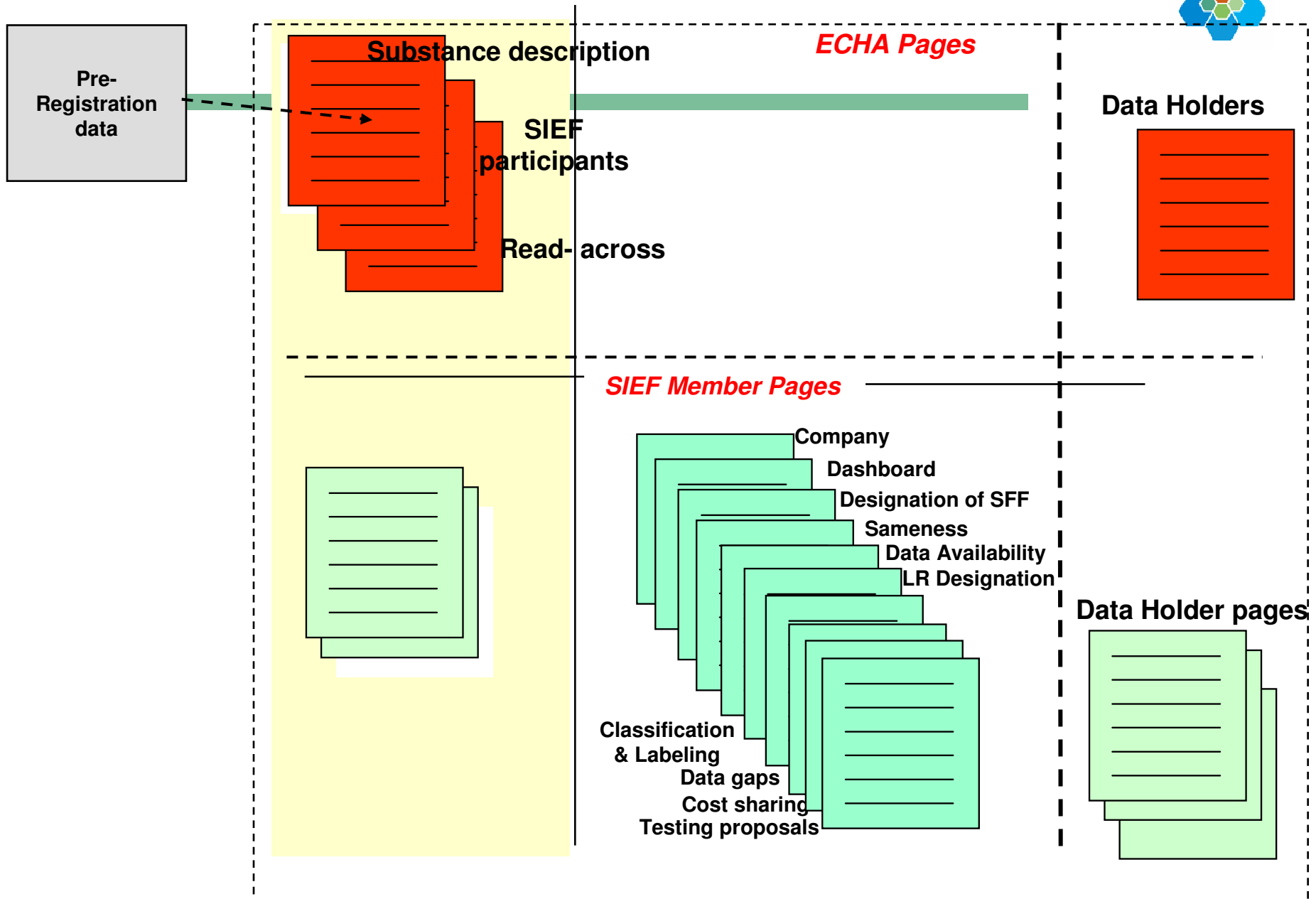
SIEF IT system Project



Project milestones:

Project kick-off	- 31 July 2007
Requirements Definition / Functional outline	- 1 Oct 2007
Tendering Process (for Development + Operations / Hosting)	- 5 Dec 2007
Decision on Business Model / IT Service Provider (IBM)	- 14 Dec 2007
Build phase kick-off	- 8 Jan 2008
Test version available	- 1 Apr 2008
Operational	- 1 Jun 2008

SIEF IT system – Information Folders



SIEF IT system - Overview

