

Agreements in the SIEF

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Reminder: agreements in the SIEF: why?



REACH defines the starting points (pre-SIEFs members) and final purpose / obligations (data sharing, Joint Submission, C&L) but not the how to do it (operational rules).

SIEF process/management (e.g. organisation of dossier preparation, cost sharing criteria, liabilities, participation to the Joint Submission) are not described in REACH, but a minimal legal framework is highly recommended.

In addition, companies may be involved in a range of SIEFs, therefore standardisation is key.



Standardised legal framework for SIEF process provided by Cefic

Agenda



- **SIEF LEGAL ARRANGEMENTS**
 - **COOPERATION/CONSORTIUM AGREEMENT**
 - **SIEF AGREEMENT**
 - **DATA SHARING AGREEMENT**

- **LETTERS OF ACCESS**

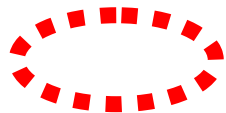
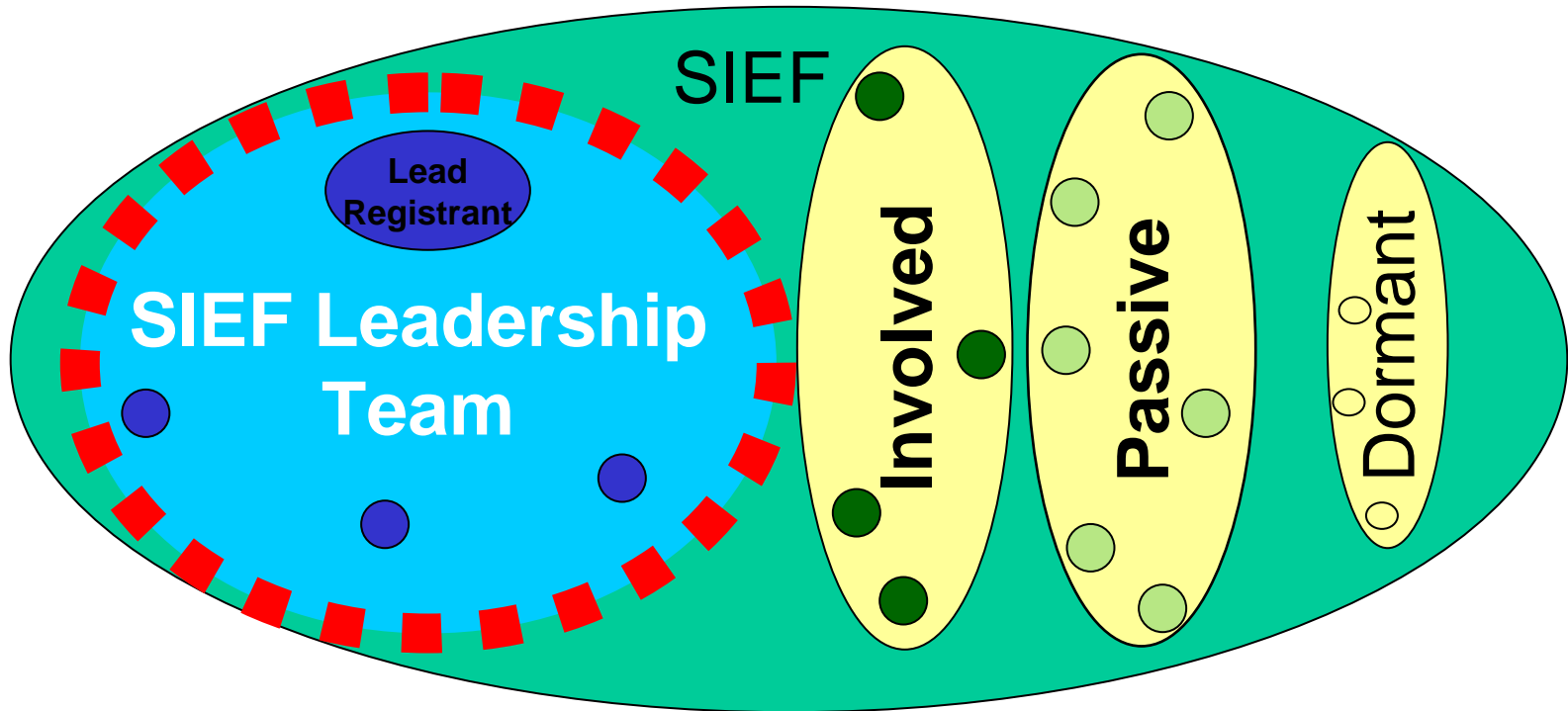
Cooperation between Lead members



- For SIEFs with **high number** of members, the formation of **consortium** has proven to be a very efficient way to organise the work with legal certainty (via a consortium agreement)
- For smaller SIEFs, a consortium may be ‘too much’
→ the work can be coordinated by a **SIEF Leadership Team** instead, composed of the active companies willing to take the lead. In this case, a **cooperation agreement** is proposed.



Cooperation agreement: no consortium in place and few Lead Members



= cooperation agreement



= Lead Members

Cooperation agreement between Lead members



The members of the SIEF Leadership Team should set up some form of contractual arrangement in order to legally structure their cooperation.

Content of the operating rules of the SIEF leadership team: e.g.

- tasks between Lead members
- data sharing mechanisms
- costs between Lead members
- confidentiality
- proxy given to the Lead Registrant to represent them in the SIEF agreement



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Why a SIEF agreement?



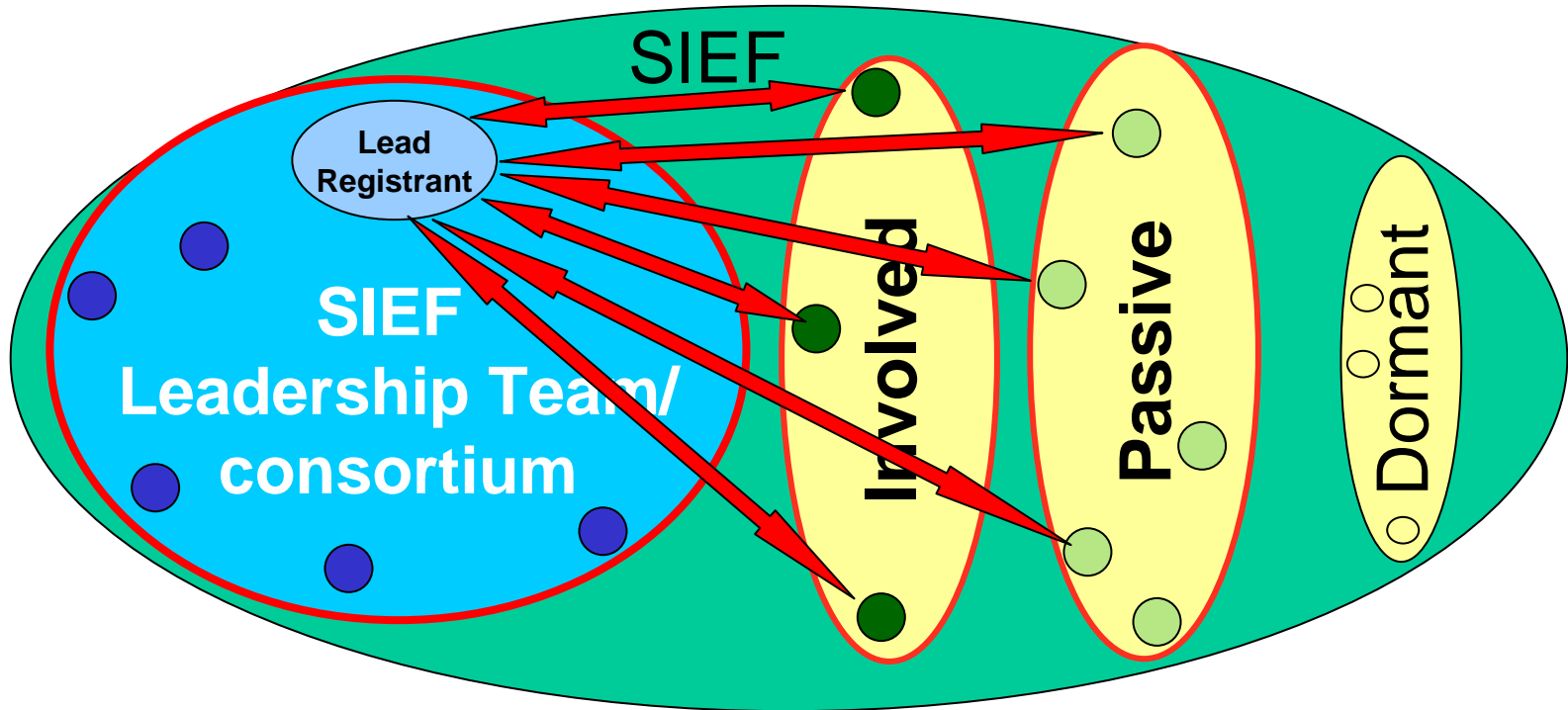
SIEF AGREEMENT = SINGLE SOLUTION: standardised legal framework for SIEF process covering:

- SIEF operating rules
- data sharing rules
- cost sharing criteria
- etc.

The SIEF members agree **in one go** on all these rules in a contractual way (**legal certainty** via binding and enforceable rights and obligations)

- Good for the LR: it defines his obligations and liabilities
- Good for the SIEF members: it provides them with a legal frame for subsequent operations involving finances, exchange of information, etc

SIEF agreement



= SIEF agreement: between the SIEF Leadership Team (via the LR) and each signatory SIEF participant

SIEF agreement: content



- gives the co-registrant access rights to the joint dossier
- describes how the costs will be shared in the SIEF
- defines the participation in the Joint submission of the Dossier
- formalises the appointment of the Lead Registrant
- defines the way communications will take place e.g. use of a particular IT-Platform
- limits the liabilities
- sets up confidentiality obligations



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Drafting by the LR and adoption in the SIEF



Quick adoption is possible:

- **Only a couple of points on cost sharing are optional in the model and subject to (legal) discussion: short drafting process by the LR/SLT.**
These points can be highlighted, the rest being industry standard (no need for long discussions)
- **As LR, use a standardised electronic process of approval/signature**

Recommendations to LR



- **Keep it simple and focus discussions on clear priorities: the SIEF agreement should only set up basic rules/principles.**
- **When exact figures are unknown, the addition of cost sharing examples (e.g. different scenarios) in the agreement is not recommended but a detailed parallel communication by the LR on cost sharing should take place.**
- **In view of a smooth and quick process of adoption, deviation from the Cefic model only when strictly necessary.**

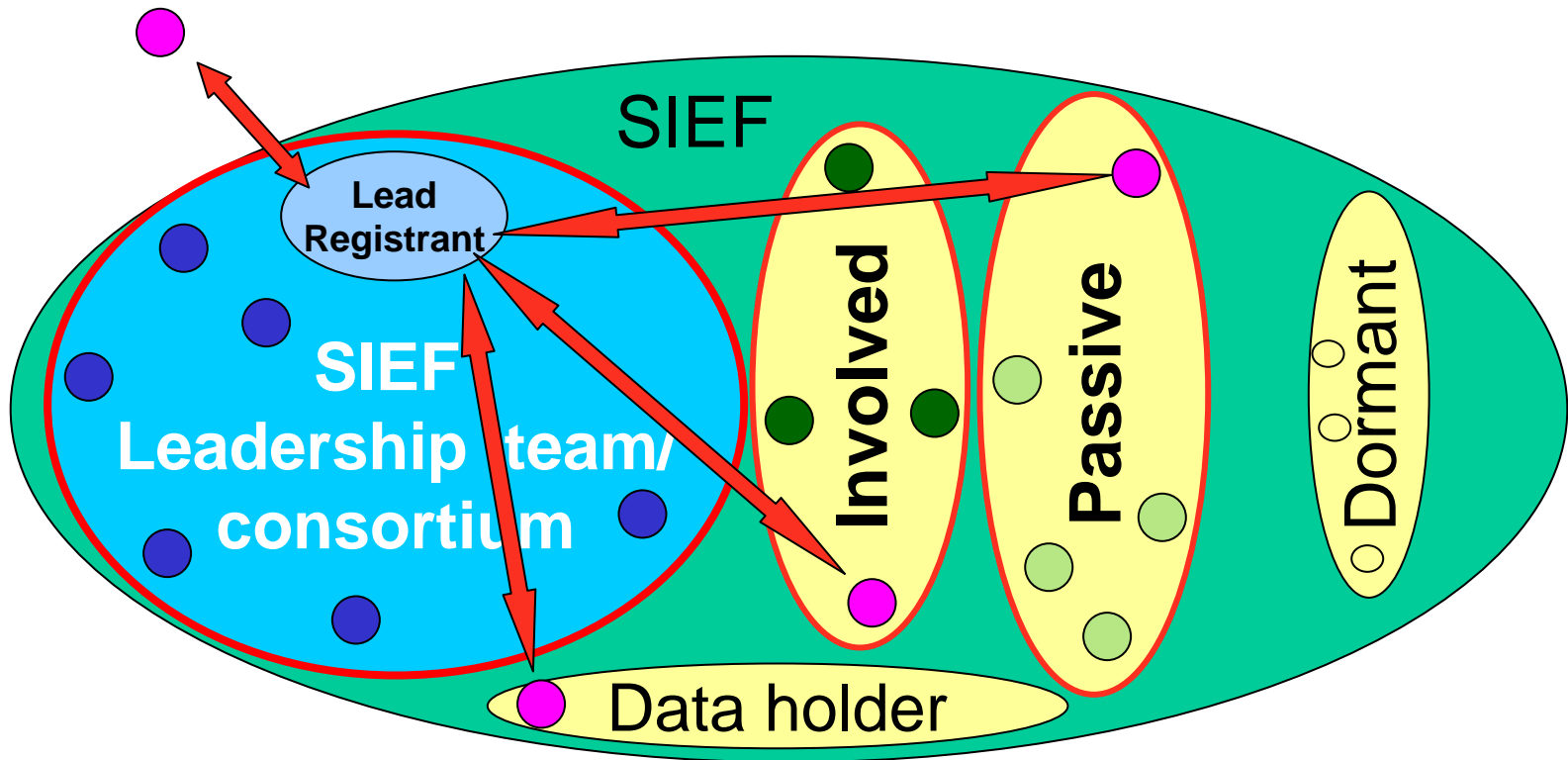


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Data sharing agreements between SLT and data owners



↔ = data sharing agreement(s) between LR and data owner(s)

● = external data owners

Data sharing agreement



- **when and why?** when existing study out of the SLT and necessary to complete the dossier
- **who ?** the LR, in representation of the SLT
- **with?** data owners in and out of the SIEF
- **object?** grant of the permission to refer to the study, upon compensation
- **scope?** one or several substances (read-across), for REACH only

Centralisation via the LR who will sub-license all the data rights to the SIEF members via the SIEF agreement so that they can refer to the full joint dossier.

The LR gets the permission to sub-license via:

- data owned by the members of the SLT: cooperation agreement
- data owned by others: data sharing agreement(s)



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SIEF agreement + Letter of Access



- The **SIEF agreement** (or the **data sharing agreement**) is the **extended contract** agreed and signed between 2 parties (re. compensation, liabilities, scope of the rights, etc).
- The **letter of access** is the reduced and simplified form that proves legitimate access rights (useful for enforcement purposes).
= unilateral declaration delivered by the LR / the data owner upon reception of the payment (kind of **formal certificate**)



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In a nutshell

Recommendation for all SIEFs :

- one **legal framework for the Lead members** (either cooperation agreement or consortium agreement)
 - one **SIEF agreement** in place between the Lead Members and the rest of SIEF members with intention to register
 - **Data sharing agreements** between the Lead Registrant and data owners whose data will be part of the Joint submission
 - **Letters of access** as ‘proof of payment’
- + models/standardised agreements available on Cefic website

2° registration phase



Lessons from 1° registration phase:

- legal certainty via binding and enforceable rights/obligations favours SIEF process (e.g. LR)
- it takes time to set up agreements, so **start asap**
- need for brief and simple provisions
- **Cefic models proven to be neutral, useful and widely used**

Many new challenges for 2013 deadline



For contractual arrangements: *let's not reinvent the wheel!*



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