CT Portal and Database

EFPIA views

Angelika Joos

AGAH, 5 December 2014

Two important set of principles

* Principle of Operational Excellence

efpia

efpia

* EFPIA/PhRMA principles for responsible data sharing

Principles for Responsible Clinical Trial Data Sharing

Our Commitment to Patients and Researchers

Biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following Principles:

- **Safeguarding the privacy of patients**
- **Respecting the integrity of national regulatory systems**
- **Maintaining incentives for investment in biomedical research**

Companies routinely publish their clinical research, collaborate with academic researchers, and share clinical trial information on public web sites at the time of patient recruitment, after new drug approval, and when investigational research programs have been discontinued.

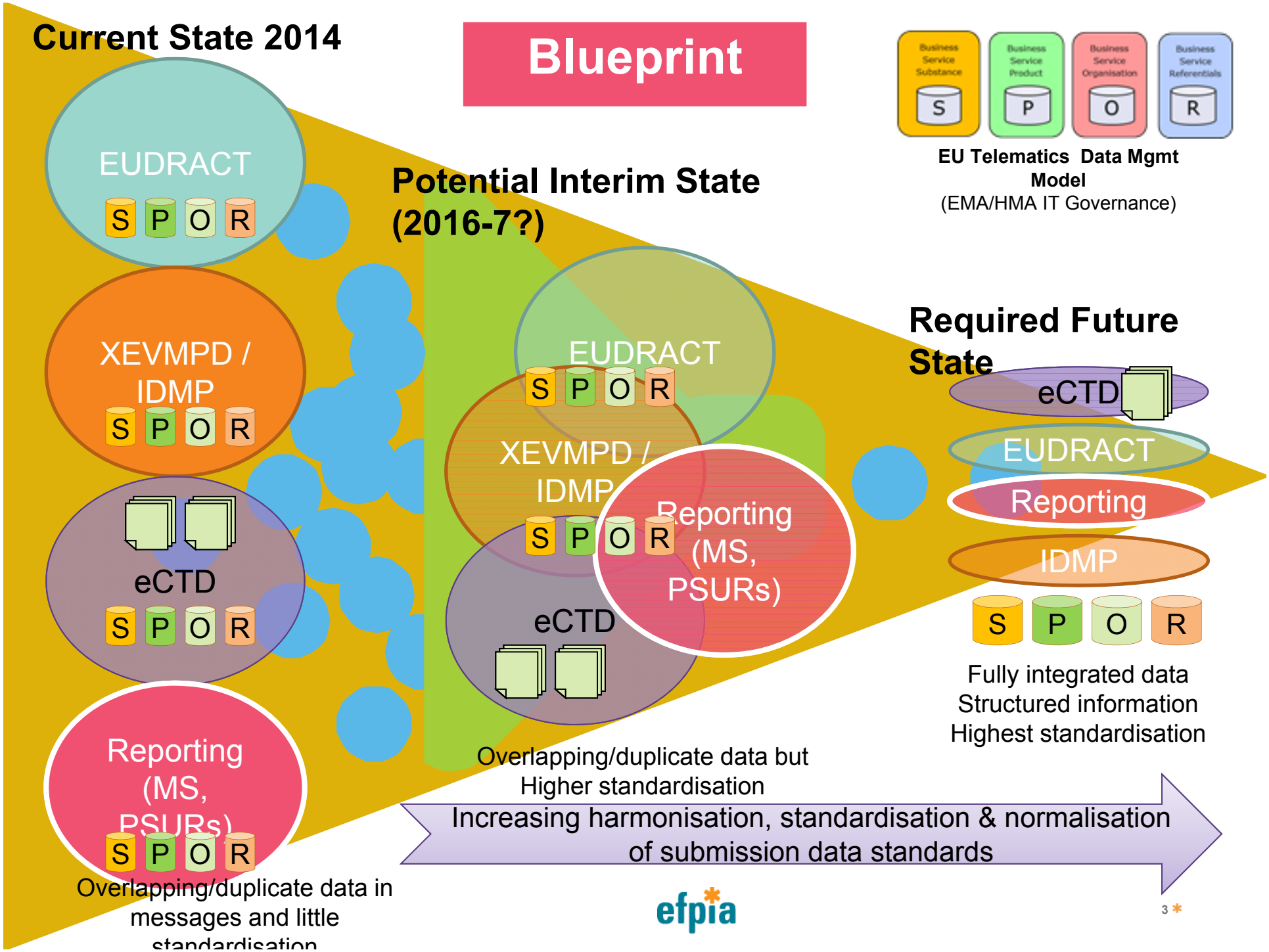
Biopharmaceutical companies will apply these Principles for Responsible Clinical Trial Data Sharing as a common baseline on a voluntary basis, and we encourage all medical researchers, including those in academia and in the government, to promote medical and scientific advancement by adopting and implementing the following commitments:

1. Enhancing Data Sharing with Researchers

Biopharmaceutical companies commit to sharing upon

Each company will establish a scientific review board that will include scientists and/or healthcare professionals who are not employees of the company. Members of the scientific review boards will participate in the review of data requests to determine whether they meet the criteria described below regarding the qualifications of the requestor and the legitimacy of the research purpose, unless a company makes an initial determination on its own to share applicable clinical trial data. Companies will publicly post their data request review process and the identity of the external scientists and healthcare professionals who participate in the scientific review board, including any existing relationships with external board members.

Companies will provide access to patient-level data and


Current State 2014
Blueprint
Business Service Substance
Business Service Product
Business Service Organisation
Business Service Referentials
S
P
O
R
EU Telematics Data Mgmt Model
(EMA/HMA IT Governance)
EUDRACT
S P O R
Potential Interim State (2016-7?)
XEVMPD / IDMP
S P O R
eCTD
S P O R
Reporting (MS, PSURs)
S P O R
Overlapping/duplicate data in messages and little standardisation
EUDRACT
S P O R
XEVMPD / IDMP
S P O R
Reporting (MS, PSURs)
eCTD
Overlapping/duplicate data but Higher standardisation
Required Future State
eCTD
EUDRACT
Reporting
IDMP
S P O R
Fully integrated data
Structured information
Highest standardisation
Increasing harmonisation, standardisation & normalisation of submission data standards
efpia
3

PhRMA
RESEARCH • PROGRESS • HOPE

efpia
European Federation of Pharmaceutical Industries and Associations

Principles for Responsible Clinical Trial Data Sharing

Our Commitment to Patients and Researchers

Biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following Principles:

- **Safeguarding the privacy of patients**
- **Respecting the integrity of national regulatory systems**
- **Maintaining incentives for investment in biomedical research**

Link: http://transparency.efpia.eu/uploads/Modules/Documents/data-sharing-prin-final.pdf

The PhRMA-EFPIA Principles supplement existing industry commitments to share clinical trial information as well as government requirements to register and post results.

Industry-wide data sharing commitments tailored to researchers, physicians, and patients

Safeguards to protect patient privacy, integrity of regulatory system, and incentives for investment in biomedical research

Implementation of the following commitments:

1. Enhancing Data Sharing with Researchers
2. **Enhancing Public Access to Clinical Study Information**
3. **Sharing Results with Patients Who Participate in Clinical Trials**
4. Certifying Procedures for Sharing Clinical Trial Information
5. Reaffirming Commitments to Publish Clinical Trial Results

2 Commitment 2:

*Enhancing **Public** Access to Clinical Study Information*

- Following approval in the US and EU
- Companies will post Clinical Study Report (CSR) synopses, at a minimum
- Will supplement data required to be posted ClinicalTrials.gov and corresponding EC/EMA sites
- Full CSRs available to researchers under terms of Commitment 1

efpia

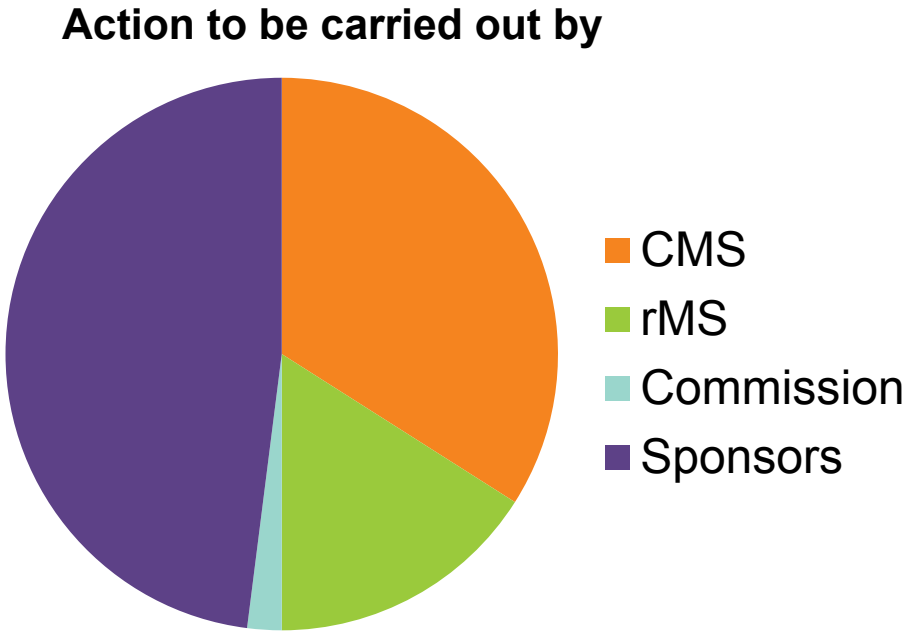
Commitment 3:

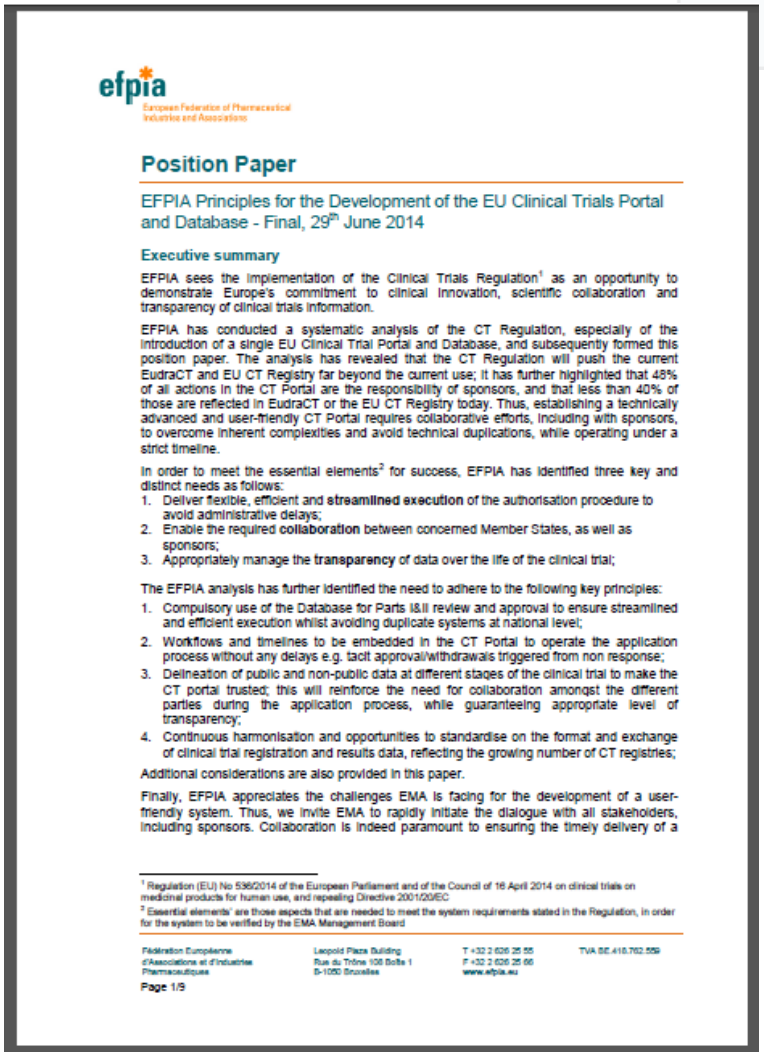
*Sharing Results with **Patients** who Participate in Clinical Trials*

- Provide factual summary of clinical trial results to research participants
- PhRMA and member companies will work with regulators to facilitate appropriate communications to patients
  - Ensure that summaries are not considered pre-approval promotion
  - Explore appropriate communications mechanisms (e.g., through investigators, web sites, and other means)

EFPIA Position on CT Portal and Database

Who will use the Portal*?





efpia
European Federation of Pharmaceutical Industries and Associations

Position Paper

EFPIA Principles for the Development of the EU Clinical Trials Portal and Database - Final, 29th June 2014

Executive summary

EFPIA sees the implementation of the Clinical Trials Regulation[1] as an opportunity to demonstrate Europe's commitment to clinical innovation, scientific collaboration and transparency of clinical trials information.

EFPIA has conducted a systematic analysis of the CT Regulation, especially of the introduction of a single EU Clinical Trial Portal and Database, and subsequently formed this position paper. The analysis has revealed that the CT Regulation will push the current EudraCT and EU CT Registry far beyond the current use; it has further highlighted that 48% of all actions in the CT Portal are the responsibility of sponsors, and that less than 40% of those are reflected in EudraCT or the EU CT Registry today. Thus, establishing a technically advanced and user-friendly CT Portal requires collaborative efforts, including with sponsors, to overcome inherent complexities and avoid technical duplications, while operating under a strict timeline.

In order to meet the essential elements[2] for success, EFPIA has identified three key and distinct needs as follows:

1. Deliver flexible, efficient and **streamlined execution** of the authorisation procedure to avoid administrative delays;
2. Enable the required **collaboration** between concerned Member States, as well as sponsors;
3. Appropriately manage the **transparency** of data over the life of the clinical trial;

The EFPIA analysis has further identified the need to adhere to the following key principles:

1. Compulsory use of the Database for Parts I&II review and approval to ensure streamlined and efficient execution whilst avoiding duplicate systems at national level;
2. Workflows and timelines to be embedded in the CT Portal to operate the application process without any delays e.g. tacit approval/withdrawals triggered from non response;
3. Delineation of public and non-public data at different stages of the clinical trial to make the CT portal trusted; this will reinforce the need for collaboration amongst the different parties during the application process, while guaranteeing appropriate level of transparency;
4. Continuous harmonisation and opportunities to standardise on the format and exchange of clinical trial registration and results data, reflecting the growing number of CT registries;

Additional considerations are also provided in this paper.

Finally, EFPIA appreciates the challenges EMA is facing for the development of a user-friendly system. Thus, we invite EMA to rapidly initiate the dialogue with all stakeholders, including sponsors. Collaboration is indeed paramount to ensuring the timely delivery of a

[1] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

[2] 'Essential elements' are those aspects that are needed to meet the system requirements stated in the Regulation, in order for the system to be verified by the EMA Management Board

Fédération Européenne d'Associations et d'Industries Pharmaceutiques
Leopold Plaza Building Rue du Trône 108 Boîte 1 B-1050 Bruxelles
T +32 2 626 25 55 F +32 2 626 25 66 www.efpia.eu
TVA BE 418.762.559

Page 1/9

efpia

* Spread per stakeholders categories based on analysis of the actions and workflows required throughout the CT Regulation

Link: http://www.efpia.eu/uploads/EFPIA_principles_CT_Portal.pdf

*

Focus on essential elements for success

- Deliver **flexible, efficient and streamlined** execution of the autorisation procedure to avoid adminstrative delays
- Enable the required **collaboration** between concerned Member States as well as sponsors
- Appropriately manage the **transparency** of data over the life of the clinical trial

Key Elements for the Successful Development of the CT Portal & DB

- Continuous dialogue, to address common needs
- Alignment with EU Telematics Strategic Goals
- Global Data Standards & IDMP considerations
- Compulsory use of the Database for Parts I&II review and approval to ensure streamlined and efficient execution whilst avoiding duplicate systems at national level
- Delineation of public and privileged data at different stages of the clinical trial to make the CT portal trusted
- Easy and clear transition rules from EudraCT to CT Portal/DB

Alignment with EU Telematics Strategic Goals

The development of the CT Portal & DB is fully aligned with the EU (EMA/HMA) Telematics Strategic Business Goals

	Strategic business goals
SG1	Seek opportunities for **technology to support efficiency in regulatory process** that will benefit both partners within the Network and their stakeholders
SG2	Seek opportunities to **avoid duplication** of resource(s) **and ensure 'value for money'** in the development and on-going usage of systems across the Network
SG3	**Optimise existing IT assets** in use **across the Network**, including knowledge sharing, analytical and reporting capability; best-practice capability and **interoperability** of solutions, where feasible
SG4	Promote **alignment with other regions** to ensure relevance in the context of global pharmaceutical regulation, where feasible (US; Japan, BRIC countries)
SG5	Promote **sharing and open access to data** repositories, interfaces, technologies, controlled terms, data dictionaries, reference terminologies etc. that can be utilised throughout the Network and make them available to stakeholders, as appropriate
SG6	Support timely delivery **IT systems**, including those required by legislation, ensuring that the solutions should seek to meet the basic needs of the Network, without introducing unnecessary complexity or additional cost.

Source: EU Telematics Strategy and implementation of the new Telematics Governance Structure - Stan van Belkum presentation to EFPIA RIT SC, 9 July 2014

Re-usable Data

- Registration and results data requirements should form the foundation for the structured data
- International harmonisation of data standards and fields for CT registration and publication of results.
  - Access to consistent information about clinical research globally and improved ability of the general public to find and understand the information which can help improving transparency and trust in clinical research.
  - Consistent with business goal of the EU Telematics strategy
  - It will significantly reduce the duplication for global sponsors in reporting CT data to multiple registries and allow sponsors to benefit from good data governance by establishing the flow of data from its sources in clinical planning systems.

Identification of IMPs

- Alignment with IDMP within CT Portal & Database is supported by EFPIA
- The EU Road Map for the development and implementation of ISO IDMP standards must consider the impact of the IDMP implementation on the EudraCT and Clinical Trial Portal and Database
- Level of details and the granularity of IDMP dataset must be proportionate to the development status of the product
  - Medicinal Products information exists only after MA
- Cross-functional multi-stakeholders consultation is important to think all issues through

Data Security

- User registration: clarity needed around concept of ‘super users’
  - Better definition needed for all stakeholders
  - Also potentially need to allow for multiple super users per single sponsor as well as at MS level
- Specific user category and access rights for Ethics Committees required
  - Avoid unnecessary hand over delays & guarantee that no national system will remain mandatory for EC submissions
  - Opportunity to ensure minimum level of MS harmonisation
- Responsible Data Sharing
  - Consistent Principles apply to CT Portal & DB and EMA policy 70
  - EFPIA welcomes specific consultation to address disclosure aspects

efpia

Submission format & tools

- Dossier Creation/Submission/Management
  - Possibility to prepare a CTA outside of the workspace
  - Allow use of existing formats, e.g. eCTD
  - Alignment of NCA's data models
- Integration with eSubmission RoadMap
- Interface with MS CTA national systems
  - Objective: avoid duplicate entries

Timely Development

- Timely development of the system essential with the need for engaging with the stakeholders early enough in a pilot

- Timely development should not compromise on the significance of delivering a successful EU portal in eyes of the Regulation

efpia

Summary

- Smart implementation of the EU Portal/DB provides the opportunity to **demonstrate Europe's commitment to clinical innovation** and to encourage collaboration that advances science and provide early treatment opportunities for patients

- Close partnership with sponsors during the IT development phase will enhance the **user friendliness** of the new system from the start

- Opportunity to implement the two important principles of **operational efficency** as well as **consistent availability of standardised content and data**

EFPIA Brussels Office

Leopold Plaza Building
Rue du Trône 108
B-1050 Brussels - Belgium
Tel: +32 (0)2 626 25 55

www.efpia.eu