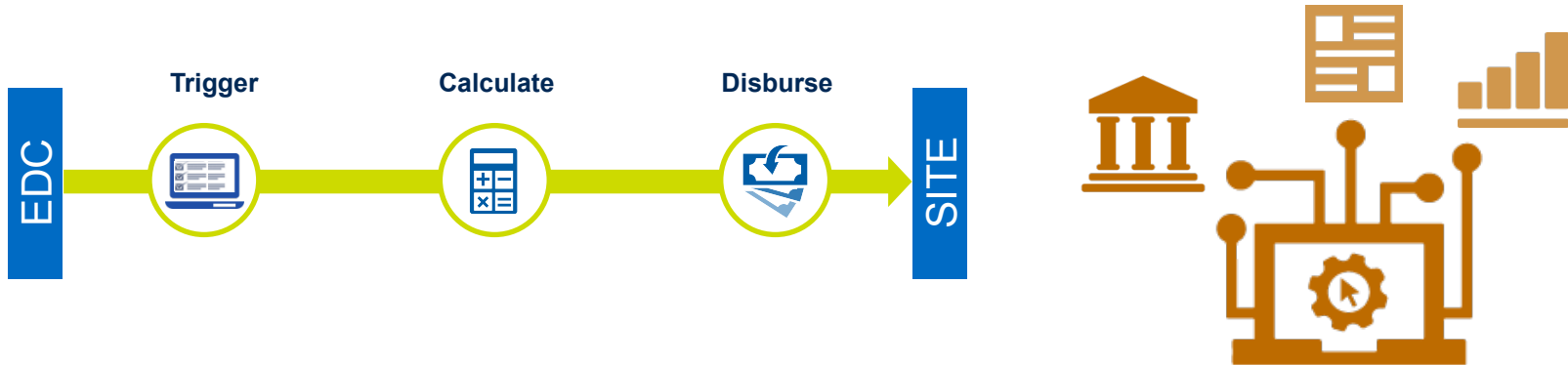




Transparency and Reporting

April Mulroney, Managing Director, Payments

Need for Global Reporting and Transparency



Accruals

- Costs Awaiting Approval (Total/ Study)
- Costs Approved
- Study Cost Accruals
- Costs by Payee (Study/Trigger)

Payments

- Payments Awaiting Approval
- Unprocessed Payments (Payee/ Study)
- Processed Payments
- Payments Information
- Funding Request

Accounting

- Full Transactional Report
- GL Export
- VAT Credit Report
- Withholding Tax Summary
- Foreign Exchange Summary

Transparency

- Open Payments
- EFPIA Disclosure
- + Other

Possible Solutions

- ❑ Excel Spreadsheets
- ❑ CTMS System
- ❑ ERP
- ❑ Specialized Technology

What are the issues?

Need for timely, accurate, transparent, compliant global reporting.

How to accomplish:

- **Visibility across your studies?**
 - Study Balances
 - Financial Accruals
 - Tax Reporting
 - Transparency Legislation
- **Accounting cycle cut offs?**
 - Monthly? Quarterly?
- **Support for financial? tax audits?**

Typical Rebuttals to Robust Processes and Technology for Quick and Accurate Reports

It is so difficult to calculate foreign exchange, tax rebates and study balances – it is almost overwhelming to begin

Sites are upset with the current payment process, but what do we do?

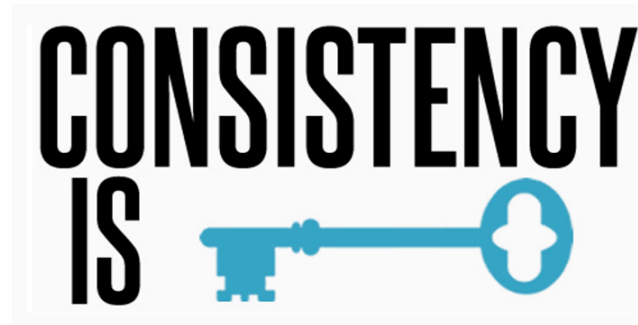
Our excel file seems to do the job

It is pre-market

We let our CRO handle it all.

Working with Multiple Vendors

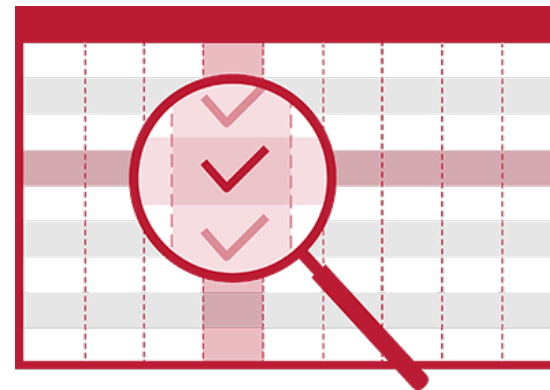
Data



Alignment of timing



Data Accuracy



Cash Flow

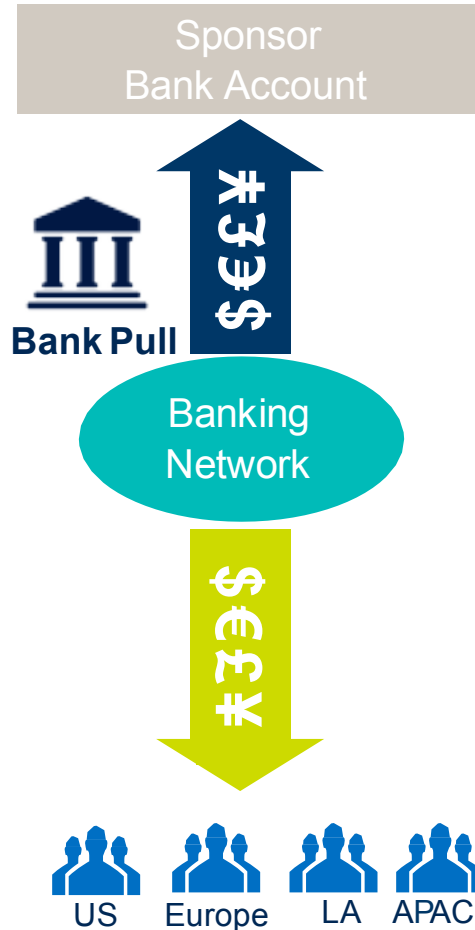
1. Forecasting

- **Timing:**
 - Study planning
 - Actuals vs. Forecast
- **Buckets:**
 - Existing enrollment
 - Projected enrollment
 - Passthroughs/Invoiceables

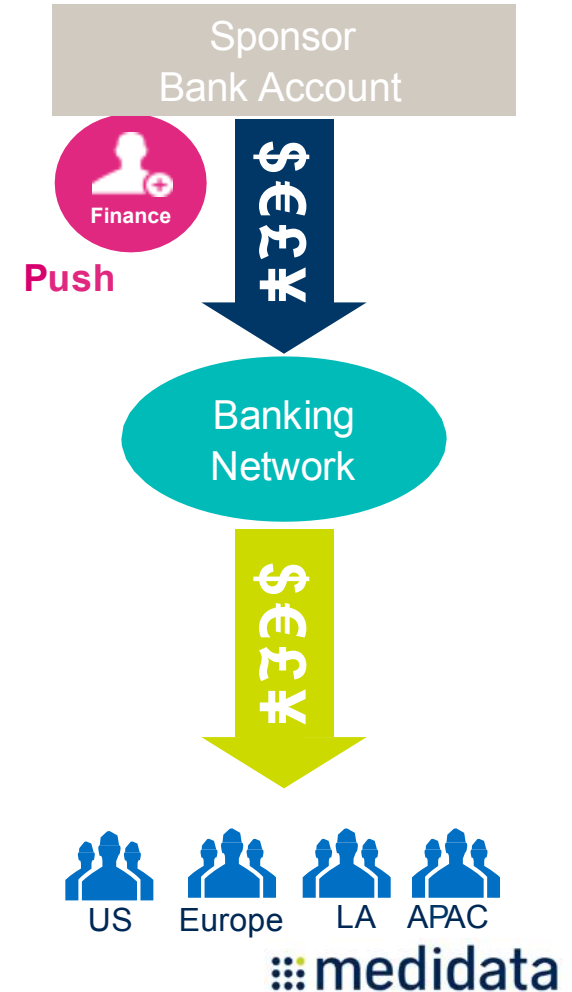
2. Escrow



Is ESCROW FREE even possible?



- “just-in-time” funding
- COMPLETE elimination of escrow



EFPIA Code Applies to 33 European EFPIA Member Associations

- First public disclosure was due 1 July 2016 for 2015 activity



Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Rep
Denmark
Estonia

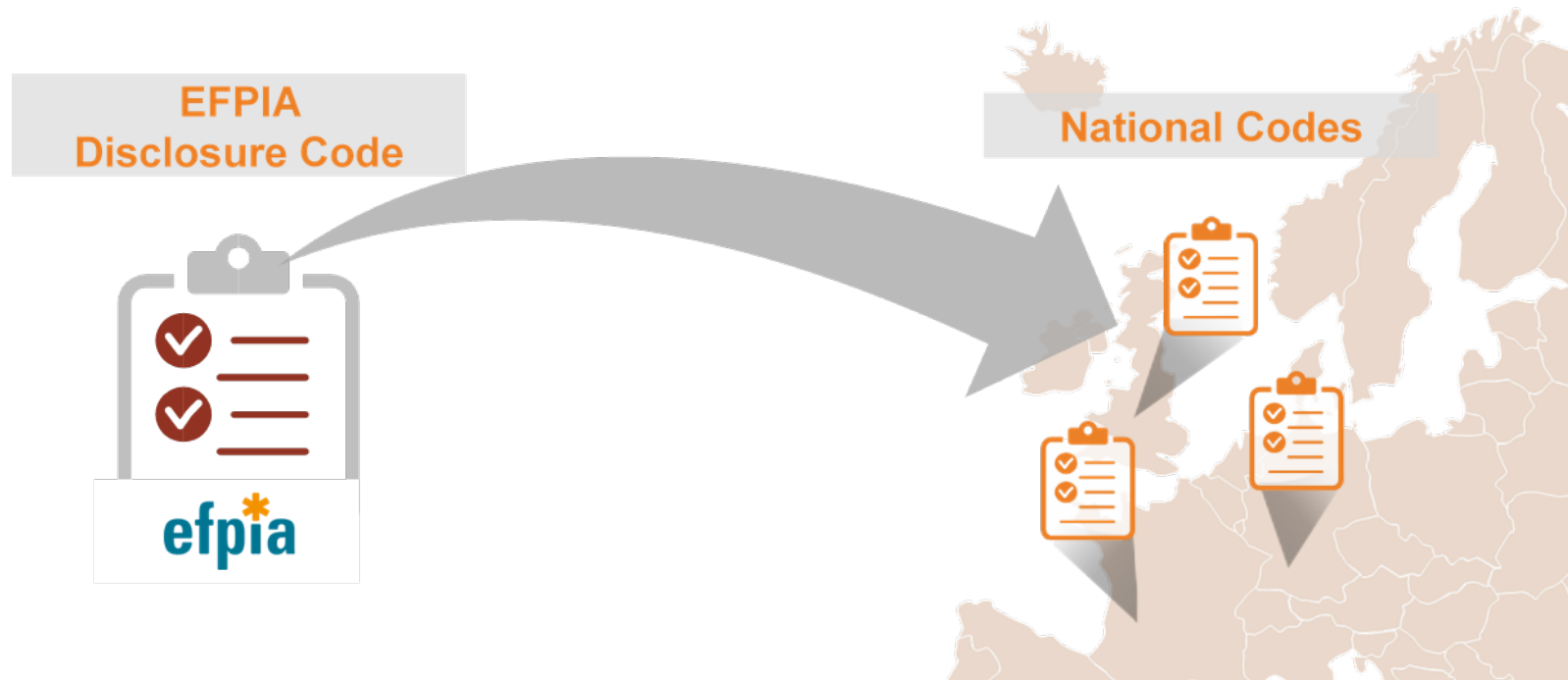
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia

Lithuania
Malta
Netherlands
Norway
Poland
Portugal
Romania
Russia

Serbia
Slovakia
Slovenia
Sweden
Switzerland
Turkey
Ukraine
United Kingdom

EFPIA Code Local Transposition Into The National Code

- All EFPIA Member Associates were required to transpose the EFPIA Disclosure Code into a National Code

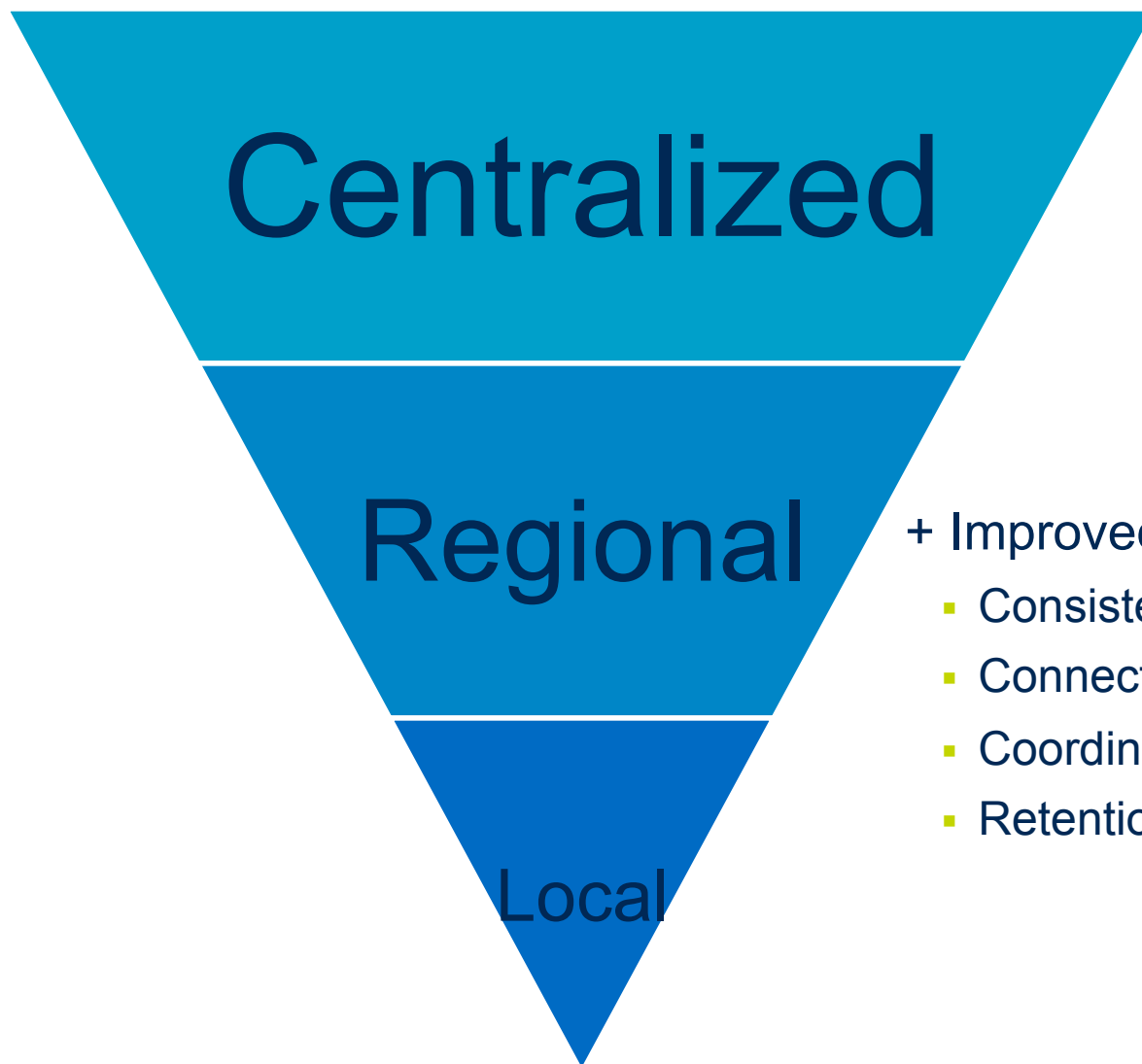


Exception: *If transposition is in conflict with applicable national laws or regulations, deviations are allowed, but only to the extent necessary to comply with the national law or regulation.*

EFPIA Code Vs. US Open Payments

	EFPIA Code	US Open Payments
Research Payments	<ul style="list-style-type: none"> Research payments loosely defined, allowing several exclusions Reporting of aggregated lump sum 	<ul style="list-style-type: none"> All research payments are included Individual disclosure (site, primary investigator, and study level)
Data Privacy	<ul style="list-style-type: none"> EFPIA “recommends” HCP consent prior to disclosure (14 local country impositions ask for consent; 6 do not require consent due to local law, 3 countries must obtain HCP consent) Aggregate disclosure can be made if consent to disclosure is not available or is revoked 	<ul style="list-style-type: none"> US are not required to obtain consent for individual disclosure as there is no local Data Privacy Act Ex-US must obtain consent, if the local Data Privacy Act require so (Eg. Switzerland)
Disclosure Platform	<ul style="list-style-type: none"> Companies may post information on their own website 9 Countries disclosing on a central platform made available on the industry member association's website (Belgium, Czech republic, Denmark, France, Ireland, Netherlands, Portugal, Russia, UK) 	<ul style="list-style-type: none"> Central disclosure platform maintained, with ability to download entire data set and use online analytic views

Approach to Global Transparency



- + Improved HCP Experience with:
- Consistent interactions
 - Connected data and systems
 - Coordinated information collection
 - Retention of HCP information