



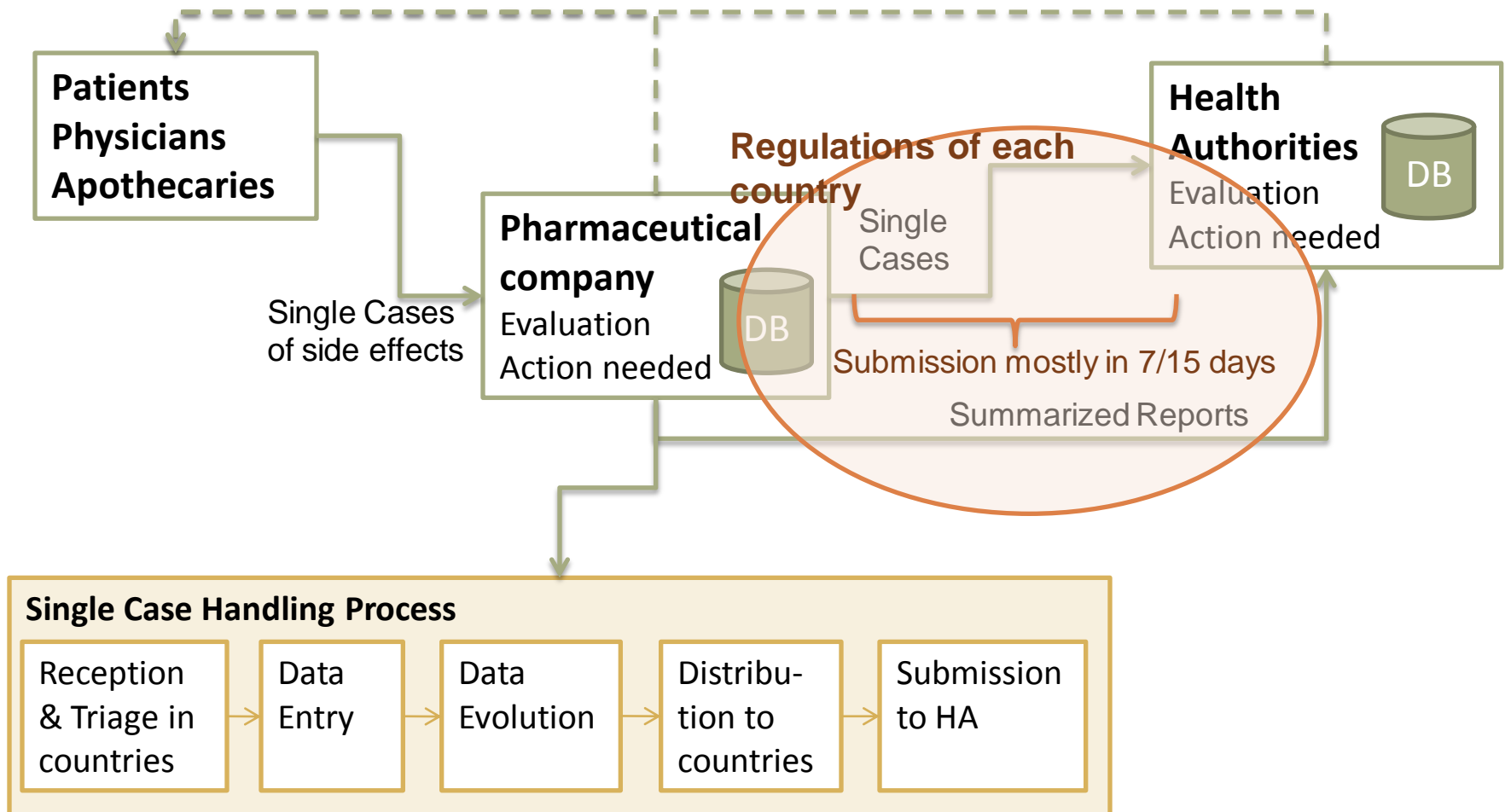
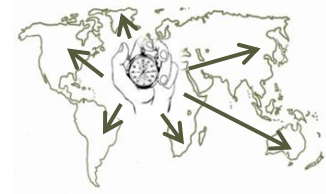
Process Compliance in Pharmacovigilance

Measurement of Single Case Submission

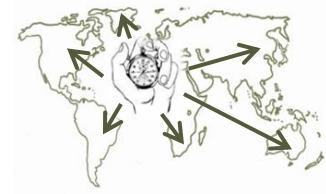
Compliance

Berlin BPM-Offensive

Pharmacovigilance System

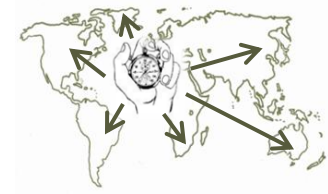


Single Case Compliance



	Submission Compliance	Case Handling Compliance
Based on	Country specific regulations	Standardized documented processes
Calculation	$\text{Compliance} = \frac{\text{Late cases}}{\text{Submitted cases}}$ <p>Late Case: $(\text{Submission date} - \text{First contact date}) > 7/15 \text{ d}$</p>	$\text{Compliance} = \frac{\text{Late processed cases}}{\text{Processed cases}}$
Required data	<ul style="list-style-type: none"> - Country specific regulations - Case attributes - First contact date, submission date 	<ul style="list-style-type: none"> - Process Documentation - Case attributes - Data of process variant
Goal	Fulfilling country specific requirements	Possibility of monitoring, early intervention and improvements of Case handling process

Experiences



Submission Compliance

- Submission Compliance was based on EU and US regulations
→ worse compliance figures for other countries/overall,
causing a collection of all country specific regulation
- Implementation of mechanism to monitor changes in regulations

Case Handling Compliance

- Mix up between Submission and Case Handling Compliance
→ no possibility for early intervention
- Collection of data from different systems → Inconsistency