A Centralized Safety Repository

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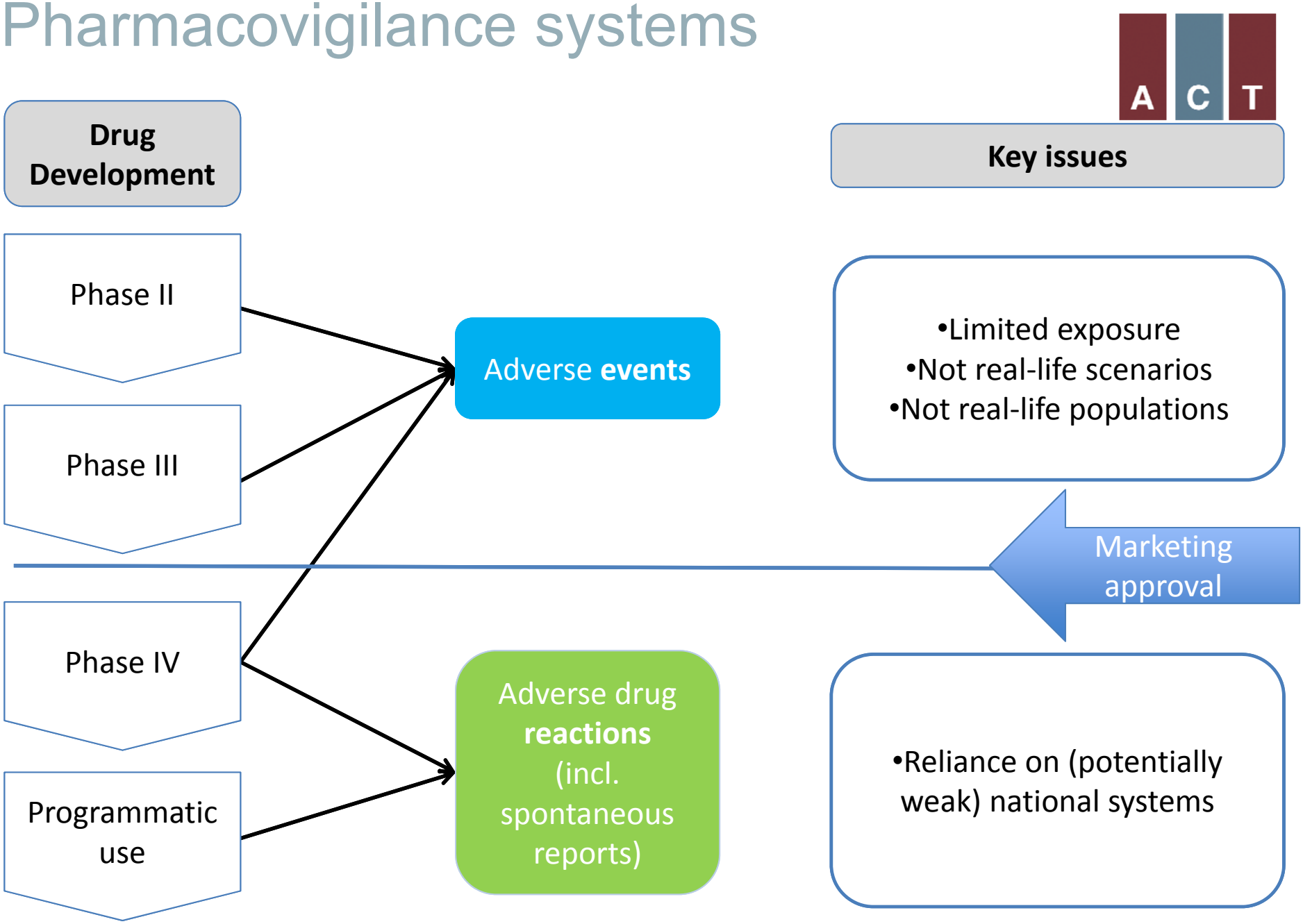
Drug Safety Repository (DSR)

Aims

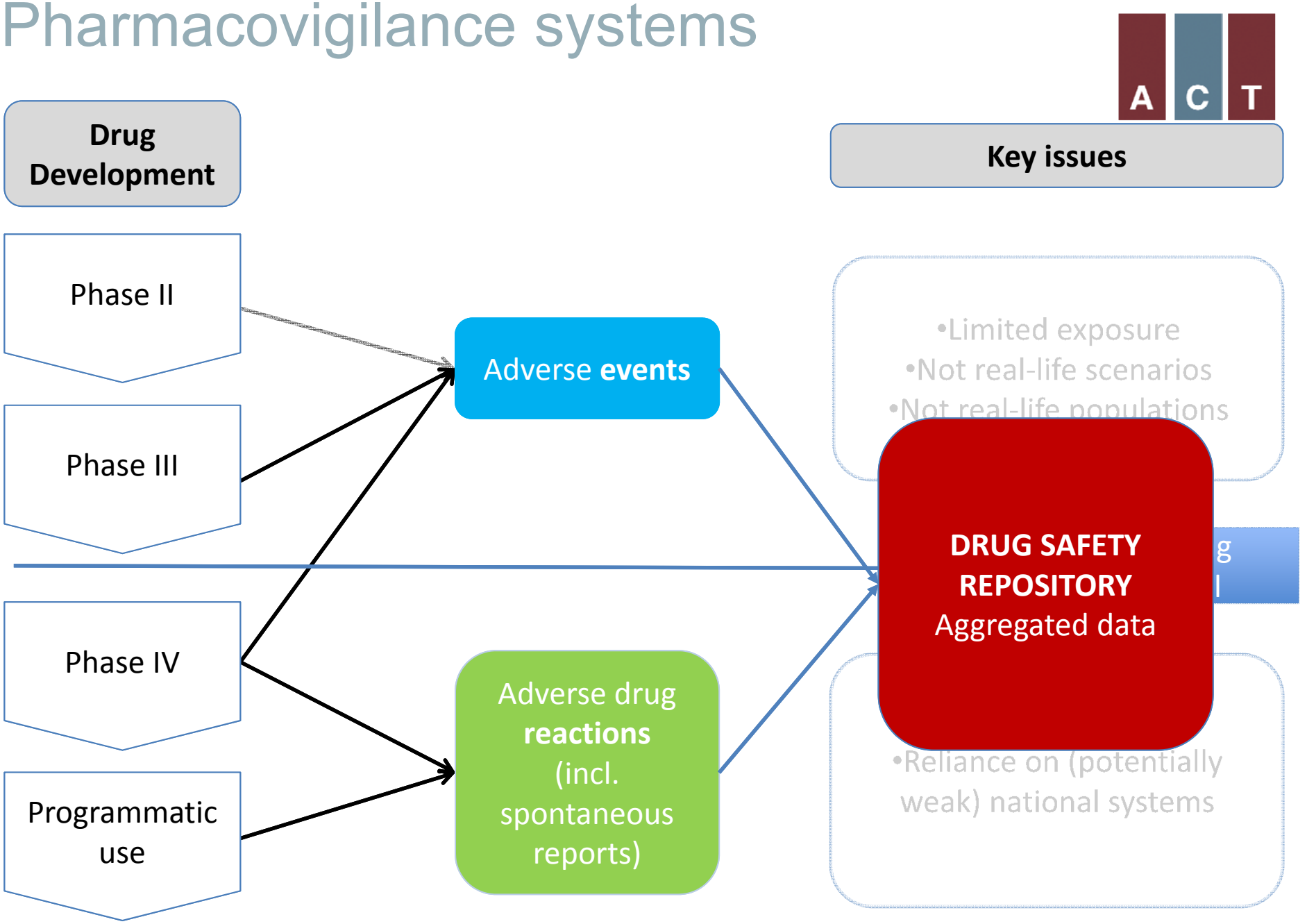
- To collect and collate safety data from a variety of sources to identify the incidence of adverse reactions and look for new signals of potential harms.

- To develop a framework to allow this surveillance to extend to other drugs & diseases.

Pharmacovigilance systems



Pharmacovigilance systems

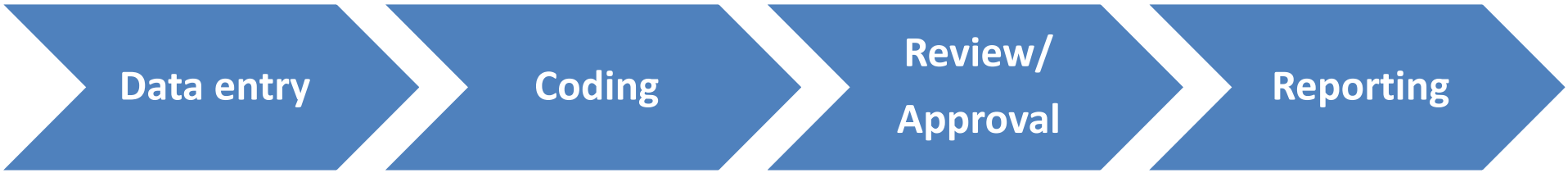


Drug Safety Repository

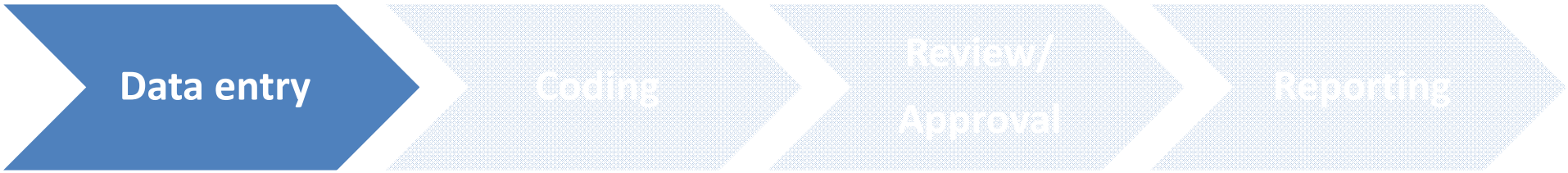
Key features

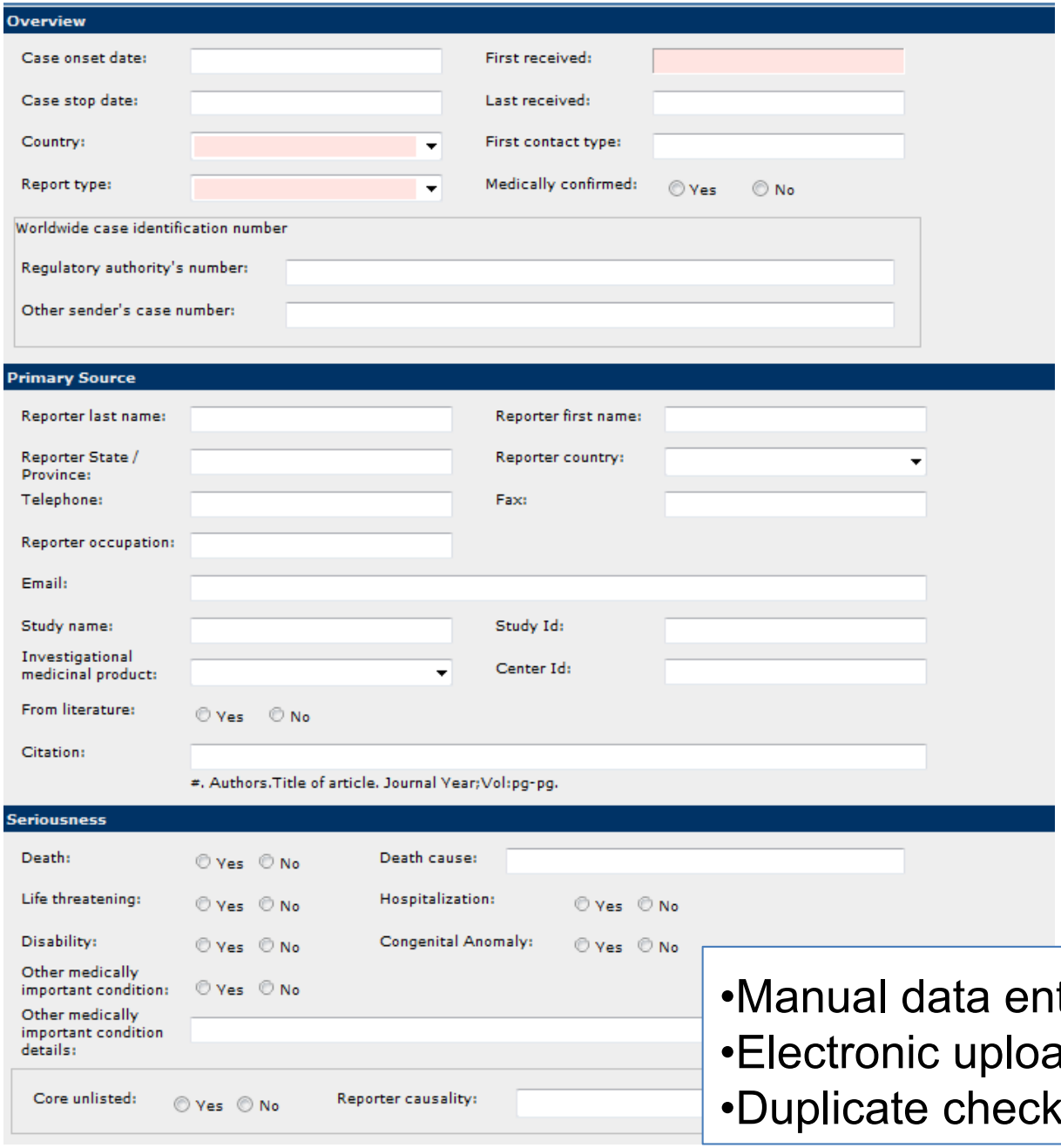
- Industry-standard web-based database for collating, recording and reporting events
- Restricted and secure access
- Integrated standardized dictionaries
- Flexible reporting tool

Case processing workflow

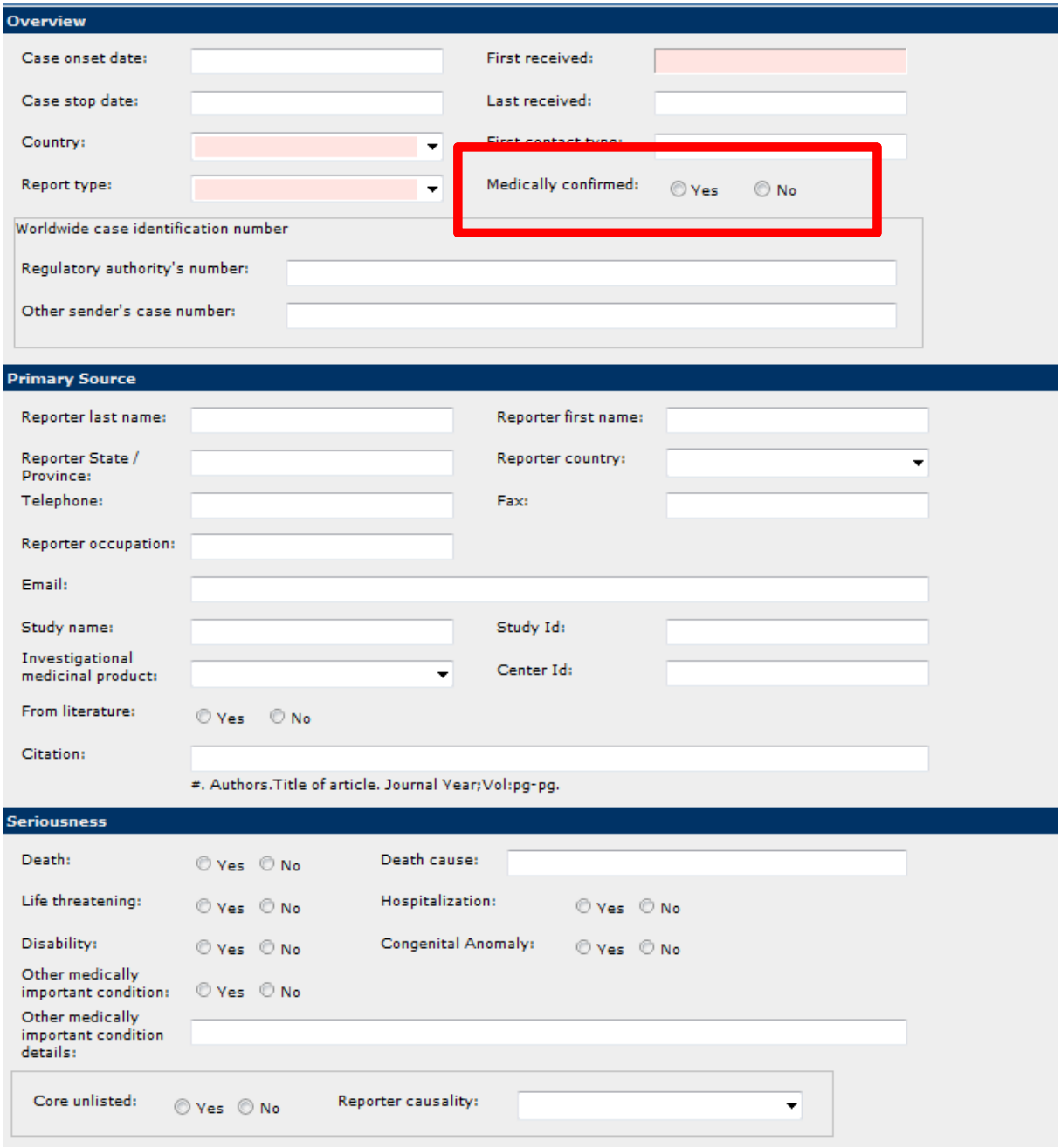


Case processing workflow

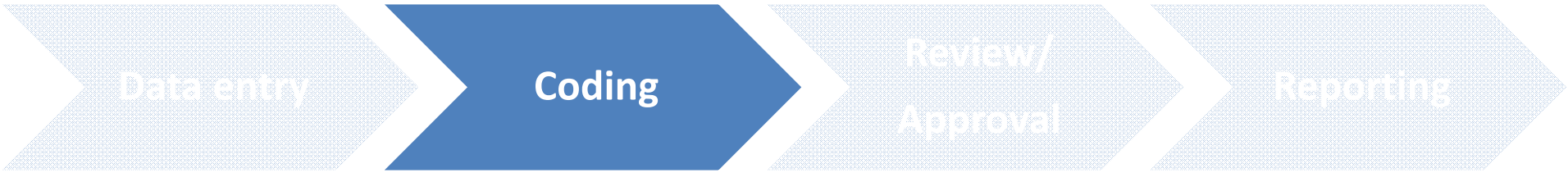




- Manual data entry
- Electronic upload
- Duplicate checking

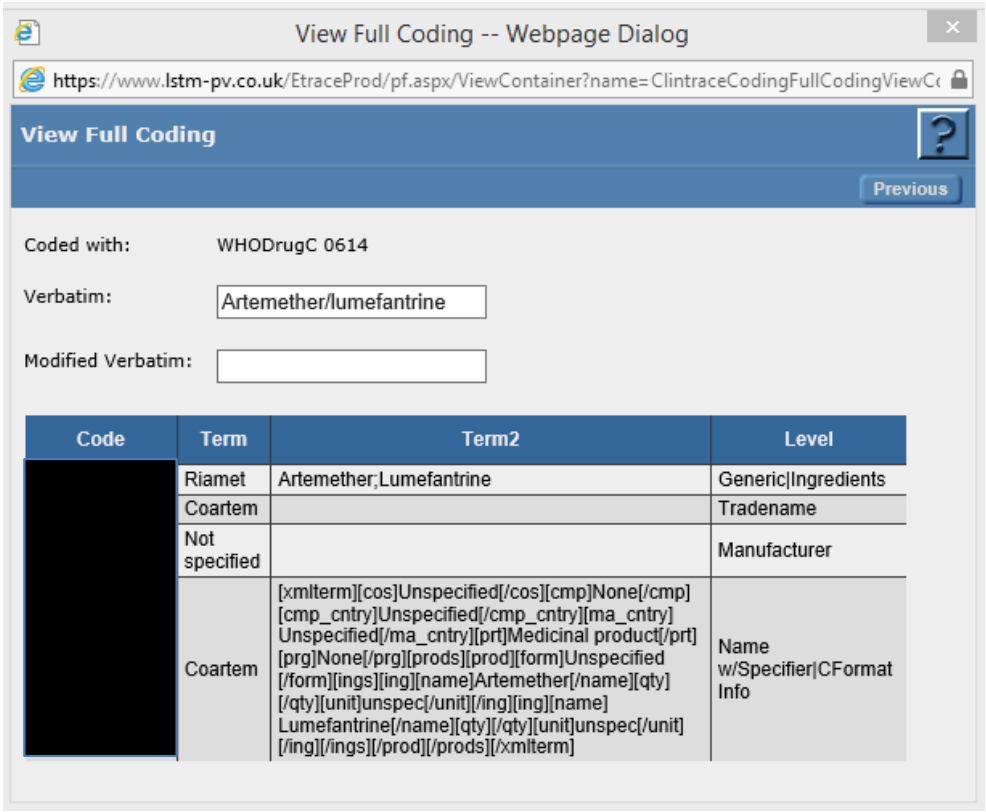


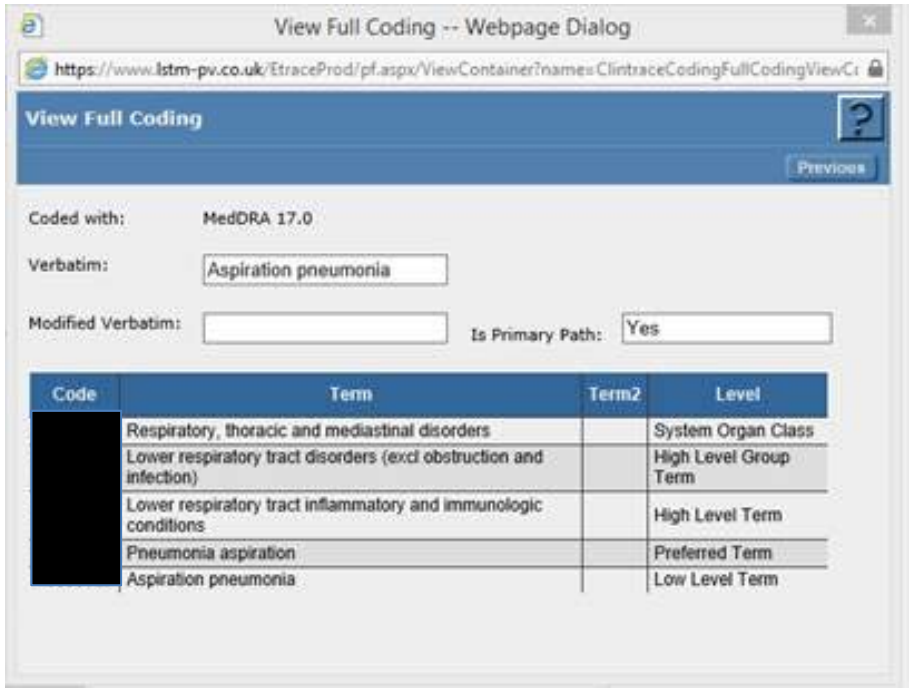
Case processing workflow



WHO Drug Dictionary

MedDRA - the Medical Dictionary for Regulatory Affairs



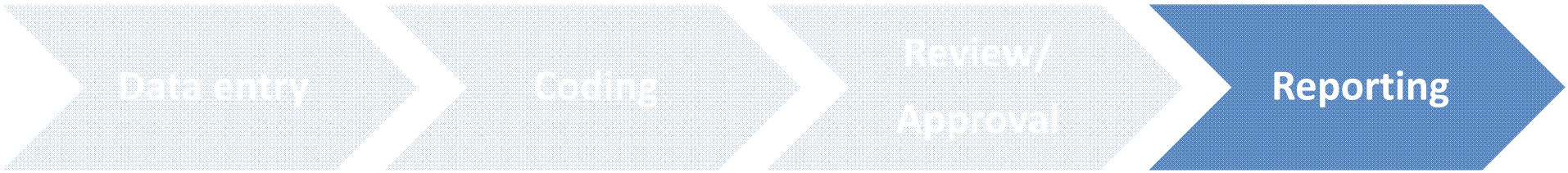


- Integrated into database
- Automated & manual coding
- Drugs
- Diseases
- Events
- Investigations

Case processing workflow

- Data entry checks
- Coding checks
- Missing data

Case processing workflow

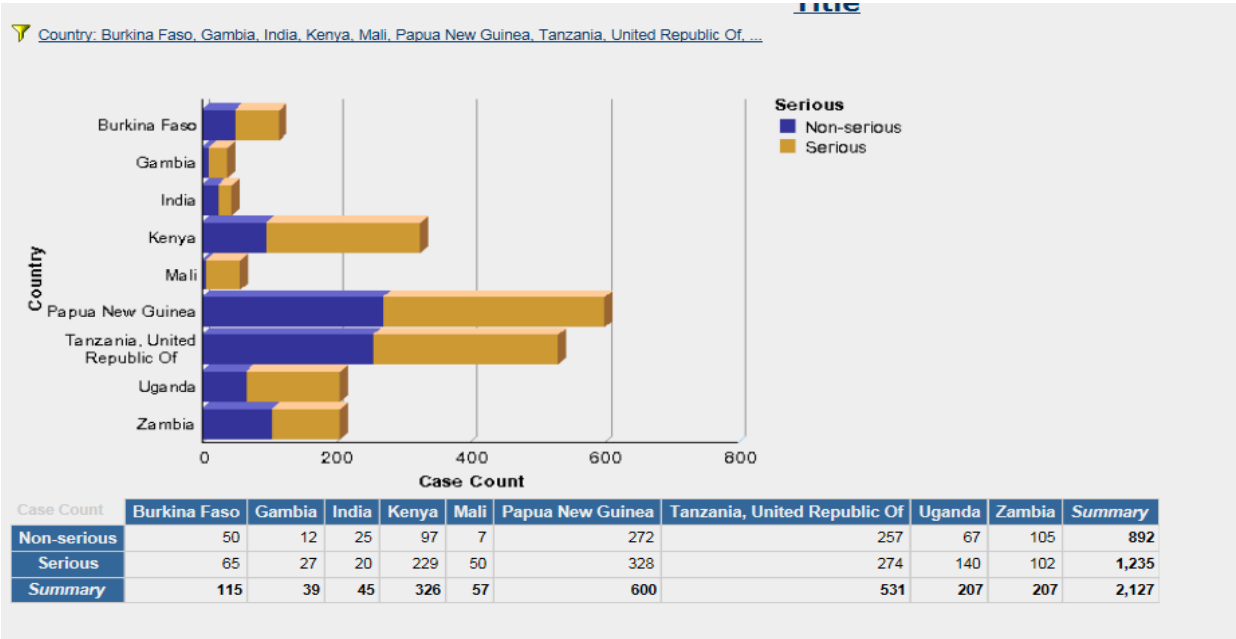


- Regulatory & ad hoc reports
- Status reports
- Case lists
- Automated & manual reports

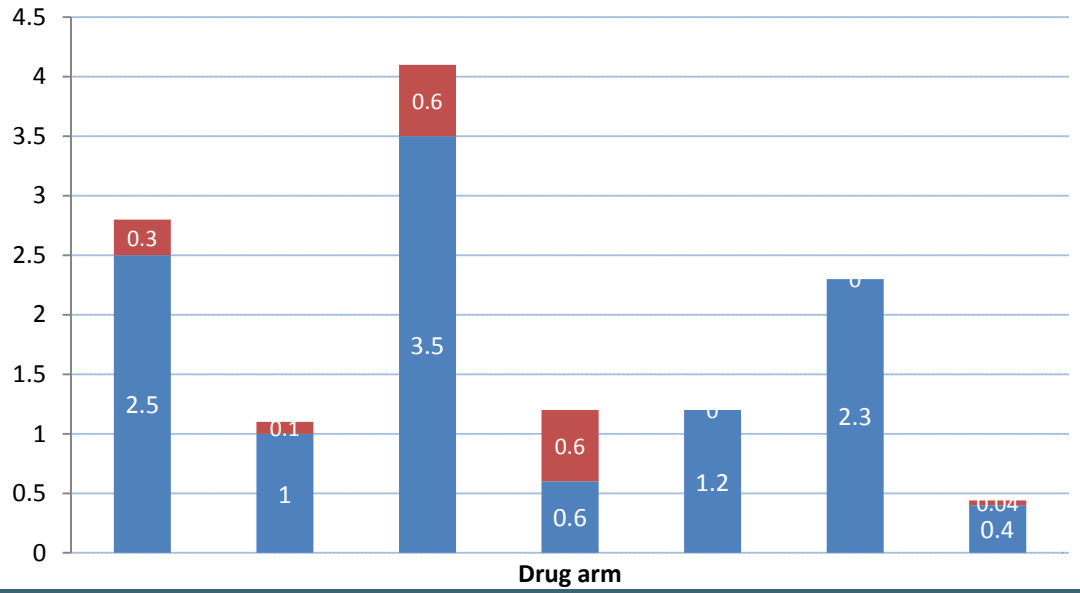
Reporting – summary tabulations

System Organ Class (MedDRA)	Drug 1	Drug 2	Drug 3	*Summary*
n	**3446**	**2931**	**1288**	***10792***
Blood and lymphatic system disorders	30 (0.9%)	0 (0.0%)	0 (0.0%)	30 (0.4%)
Cardiac disorders	1 (0.0%)	2 (0.1%)	0 (0.0%)	3 (0.0%)
Eye disorders	0 (0.0%)	3 (0.1%)	3 (0.2%)	6 (0.1%)
Gastrointestinal disorders	12 (0.3%)	155 (5.3%)	32 (2.5%)	199 (2.6%)
General disorders and administration site conditions	7 (0.2%)	61 (2.1%)	3 (0.2%)	71 (0.9%)
Hepatobiliary disorders	0 (0.0%)	3 (0.1%)	0 (0.0%)	3 (0.0%)
Infections and infestations	227 (6.6%)	24 (0.8%)	10 (0.8%)	261 (3.4%)
Injury, poisoning and procedural complications	5 (0.1%)	0 (0.0%)	1 (0.1%)	6 (0.1%)
Metabolism and nutrition disorders	6 (0.2%)	3 (0.1%)	2 (0.2%)	11 (0.1%)
Musculoskeletal and connective tissue disorders	0 (0.0%)	1 (0.0%)	2 (0.2%)	3 (0.0%)
Nervous system disorders	39 (1.1%)	54 (1.8%)	15 (1.2%)	108 (1.4%)
Psychiatric disorders	0 (0.0%)	5 (0.2%)	1 (0.1%)	6 (0.1%)
Renal and urinary disorders	0 (0.0%)	2 (0.1%)	0 (0.0%)	2 (0.0%)
Reproductive system and breast disorders	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.0%)
Respiratory, thoracic and mediastinal disorders	4 (0.1%)	16 (0.5%)	0 (0.0%)	20 (0.3%)
Skin and subcutaneous tissue disorders	1 (0.0%)	18 (0.6%)	2 (0.2%)	21 (0.3%)
Vascular disorders	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.0%)
Summary	333 (9.7%)	352 (12.0%)	80 (6.2%)	765 (10.0%)

Reporting - graphs



Case Count	Burkina Faso	Gambia	India	Kenya	Mali	Papua New Guinea	Tanzania, United Republic Of	Uganda	Zambia	*Summary*
Non-serious	50	12	25	97	7	272	257	67	105	**892**
Serious	65	27	20	229	50	328	274	140	102	**1,235**
Summary	**115**	**39**	**45**	**326**	**57**	**600**	**531**	**207**	**207**	**2,127**



Reporting - line listings

Serious events

System Organ Class (MedDRA)	Sex	Age Group	Event as reported	Preferred term (MedDRA)	Intensity	First dose to onset	Outcome
Blood and lymphatic system disorders	FEMALE	Adult	Anaemia	Anaemia	Life threatening	12 weeks 1 day	Recovered
Congenital, familial and genetic disorders	MALE	Neonate	Cleft palate and lip	Cleft lip and palate	Moderate	NA	Not Recovered
Renal and urinary disorders	FEMALE	Infant	Acute renal failure	Renal failure acute	NA	18 weeks 5 days	Fatal
	FEMALE	Adult	Unable to pass urine	Dysuria	SEVERE	5 days	Recovered

Non-serious events

System Organ Class (MedDRA)	Sex	Pt Id	Event as reported	Preferred term (MedDRA)	Intensity	Onset	Outcome
Gastrointestinal disorders	MALE	Child	Diarrhoea	Diarrhoea	Moderate	1 day	Recovering
	FEMALE	Adult	Vomiting	Vomiting	Mild	30 minutes	Recovered
Nervous system disorders	FEMALE	Adult	Headache	Headache	Moderate	1 day	Recovered
	FEMALE	Adult	Dizziness	Dizziness	Mild	60 minutes	Recovered
Musculoskeletal and CT disorders	MALE	Adult	Muscle pains	Myalgia	MILD	2 days	Recovered
Renal and urinary disorders	FEMALE	Child	Dark urine	Chromaturia	MILD	4 days	Recovering

Current status

- Validated
- Contains >3000 case reports predominantly from ACTc and MiPc
- Reporting to DSMBs, ethics committees, manufacturers tried and tested
- Providing PV services to other malaria studies
- Standardization and pooled analysis remains a challenge
- Potential future collaborations – other investigators & Consortia, other pooled data initiatives (e.g. WWARN)…..

Thank you for joining us!

Recording will be shared. Please ensure you are on our mailing list:

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For any questions or comments, contact

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