



# Translational safety intelligence

**Anticipate adverse drug reactions and identify suitable safety biomarkers to plan safe clinical trials from the start.**

**De-risk clinical trials with OFF-X translational safety intelligence and analytics:**

**01 Design safe, successful trials**

Understand how the safety profile of your drug may be influenced by patient populations.

**02 Act fast**

Enable mechanistic deconvolution of unexpected safety findings to support mitigation strategies.

**03 Anticipate risk factors**

Benchmark the safety profile of competitors' drugs and targets as they advance in development.

**04 Increase chances of success**

Define the right endpoints and select the most suitable safety biomarkers.

Figure 1: Compare drug safety profiles by target class.

**Comparative drug safety evidence**  
 Comparing 19 FLT3 Inhibitors

Filter Columns View AE/SOC Number of alerts Heat map Sort drugs Highest phase

Drug type | Product category/modality | Drugs/biologics (19) Clear all filters

Adverse event - System Organ Class	OFF-X Target/Class Score	midostaurin Launched 2017	gilteritinib Launched 2018	ponatinib Launched 2019	quizartinib Launched 2019	levitinib Launched 2022	sonkeplamb Pre Registered	evacetinib Phase II	fosatinib Phase II	lazaritinib Phase I/II	ENMD-91593 Phase I	4545DEM Phase III	lusectinib Phase III	negotinib Phase III	ispartinib Phase III	perforinib Phase III	EE-1203-04 Phase I	EN-1501 Phase I	midostaurin Discontinued	Lanzotinib Discontinued	Tools	
Fatigue - General disorders and administration site conditions	Very high	12	28	17	15	8		3	1	2	5	2	4				2	2	2	6	2	
Oedema peripheral - General disorders and administration ...	Very high	4	13	10	8	13		2			1	1	1						2	1		
Alanine aminotransferase increased - Investigations	High	9	32	26	14		5	5	3	1	2		2		1		2	2		6	1	
Anaemia - Blood and lymphatic system disorders	High	16	25	8	23	20	4	2	4	3	2	1	4	1			2	1	2	6		
Arthralgia - Musculoskeletal and connective tissue disorders	High	3	13	7	1			1	1											1		
Aspartate aminotransferase increased - Investigations	High	5	34	24	9		5	5	1	1	2		1				2	3	1	7	1	
Diarrhoea - Gastrointestinal disorders	High	24	33	9	19	19	3	8	3	5	4	1	5	1	2		2	3	1	5	1	
Gastrointestinal disorder - Gastrointestinal disorders	High	6	8	2	1	4				1							1					
Infection - Infections and infestations	High	2	8		10	4	1			1							1			1		
Mucosal inflammation - General disorders and administrat...	High	5	4	2	2			1			1						1					
Nausea - Gastrointestinal disorders	High	30	19	11	26	12	2	10	1	4	4	1	6	1	2	2	3	2	4	1		
Neuropathy peripheral - Nervous system disorders	High		1	2					1				1						1			

Figure 2: Monitor potential liabilities and correlate findings as your drug moves from preclinical to clinical - or from healthy volunteers to patients.

**Translational safety**  
 Showing 25 System Organ Classes

Filter Columns View SOC

System Organ Class	OFF-X Target/Class Score	Biological Role & Preclinical Pharmacological Evidence					Clinical Pharmacological Evidence							Tools						
		Target Expression	Human Genetic variants	KO/KO Animal data	Inhibits Bcl-2 / Patient samples	Preclinical	Phase I	Phase II	Phase III	Clinical Regulatory	Phase labeling	Phase not specified								
Investigations	High		8			39	7	245	28	199	11	59	2	74	2	54	3	100	6	
Gastrointestinal disorders DME	Very high		13	Species 1	2	25	8	227	28	176	15	83	2	93	2	258	3	225	7	
Pregnancy, puerperium and perinatal conditions	Low					22	2							4	2			2	1	
General disorders and administration site conditions DME	Very high		2	Species 1	4	17	10	150	28	106	14	47	2	51	2	113	3	97	6	
Immune system disorders DME	Very high		16	Species 1	4	Species 2	2	32	17	10	3	16	2	15	1	201	2	120	3	
Cardiac disorders DME	Very high			Species 1	3	Species 1	3	19	9	23	6	13	1	13	2	192	2	111	2	
Hepatobiliary disorders DME	Very high		6			13	4	33	9	25	5	18	2	26	2	106	2	96	4	
Skin and subcutaneous tissue disorders DME	Very high		6			11	2	182	28	98	13	70	2	120	2	242	3	273	7	
Blood and lymphatic system disorders DME	High		23	Species 1	2	Species 1	1	34	15	28	10	10	1	30	2	82	3	47	4	
Endocrine disorders	Very high		8			9	2	84	17	52	8	65	2	53	2	280	3	217	5	
Renal and urinary disorders DME	High					9	2	24	10	28	6	6	1	21	2	59	2	48	3	

Figure 3: Understand how your drug's safety profile is influenced by patient characteristics, including head-to-head comparison by condition.

Master view | Translational safety | **Clinical patient safety** | Real-world evidence analysis | Mounting evidence chart

Comparing 32 conditions

Filter | 3 hidden columns | View: AE/SOC | Data type: Patient condition | Sort conditions: Alphabetically

Adverse event * System Organ Class	OFF-X Drug Score ↓	Aortic valve disease	B cell lymphoma	Chronic lymphocytic leukemia	Diffuse large B-cell lymphoma	Follicle center lymphoma	Immediate type hypersensitivity	Larynx tumor	Lymphadenopathy	Lymphoma	Lymphoplasmacyct lymphoma	Macroglobulinemia	Mantle cell lymphoma	Marginal zone B-cell lymphoma	Marginal zone lymphoma	Metastatic bladder cancer	Metastatic head and neck cancer	Tools
Anaemia * Blood and lymphatic system disorders	Very high	4	7	29	10	3		1	1	7	4		13	3		1	1	
Arthralgia * Musculoskeletal and connective tissue disorders	Very high		4	26	10	1				9	4	4	4	2	3			
Carcinogenicity * Injury, poisoning and procedural complica...	Very high	5	4	25	6	3				4	3	1	4	3				
Contusion * Injury, poisoning and procedural complications	Very high	1	2	22	11	2				10	4	1	6	3				
Diarrhoea * Gastrointestinal disorders	Very high	5	7	41	16	4			1	13	6	2	13	3	1	1		
Fatigue * General disorders and administration site conditions	Very high	3	5	22	6	4		1		3	4	2	9	3	2	1	1	
Haemorrhage * Vascular disorders	Very high	7	5	38	13	4				12	6	3	9	5	1			
Headache * Nervous system disorders	Very high	5	9	42	16	4			1	12	6	2	15	3	2	1		
Hypertension * Vascular disorders	Very high	3	4	33	16	3				15	2	2	6	4				
Infection * Infections and infestations	Very high	5	4	30	8	3			1	9	3	1	6	3				
Nausea * Gastrointestinal disorders	Very high	3	4	27	9	3			1	9	3		4	3		1		





## OFF-X empowers clinical researchers to design safe and successful trials with unrivalled, high-quality curated data:



Spend less time gathering data so you can focus on what matters most.

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Access expertly curated data from a broad range of sources, including journal articles, conferences, company communications, clinical trial registries, regulatory documents and FAERS/JADER.

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Keep up with critical safety information impacting your assets with daily updates (including announcements of clinical holds due to serious adverse events or interim clinical trial results)

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Visualize and digest insights faster with intuitive comparison tables and dashboards.

## About Clarivate

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