

IQVIA Vigilance Periodic

Today's reality

Today, the generation of standard Periodic reports is complex due to continually evolving requirements. Case inclusion criteria are difficult to set, reports are often supported by black box query logic, and case versions and submission history are challenging to track in case processing, making it hard to have the right cases. Even a simple task like identifying a case during processing for periodic reporting and it being automatically included is difficult.

Out-of-the-box reports and line listings provide all regulatory required reports and formats.

Solution

IQVIA Vigilance Periodic provides out-of-the-box reports and line listings that reduce the effort needed to provide standard reports. All reports and line listings are regularly updated for all regulatory required formats, removing your need to track regulations and update reports accordingly.

Vigilance Periodic offers user friendly inclusion and exclusion criteria, including relevant cases identified during case processing. Report templates can be created, copied, and made available to different teams. Vigilance Periodic has full case version and field version history, allowing users to create point in time reports for any period and allowing you to re-create the same report if needed at any time, for example during an audit.



Vigilance Periodic methodology



Vigilance Periodic provides a simple user interface to create and manage reports.



Users can easily include and exclude cases.



The correct version of the case and the case data is managed by the system through field-level version control.



All standard reports and line listings are out of the box and regularly updated, removing the need for users to manage and track regulations and update standard reports accordingly.



Templates are used to create new reports and can be saved for future use, reducing the time to set up and manage reports.

Discover a collaborative approach to periodic reporting that streamlines key activities entirely within the system, replacing offline, siloed, and manual exercises.

Key benefits



බිලි Simplified query logic

- · Avoids historical pitfalls seen with legacy systems.
- Understand the data the system creates.
- Define cases to include during case processing.



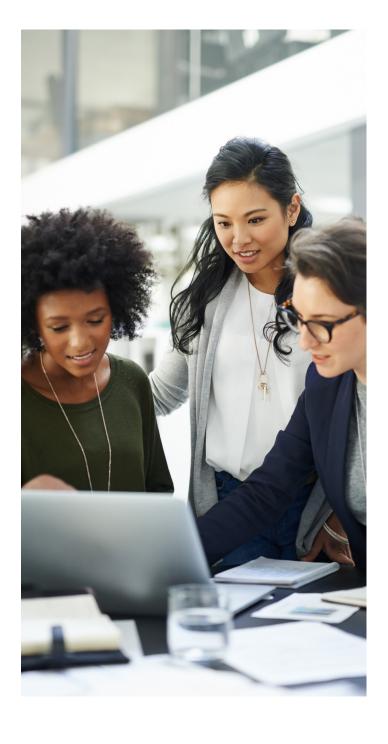
Field-level version control

- Easy-to-create reports for any point in time.
- Simple-to-recreate reports in the future.



Security and data protection

 System ensures respect for data privacy based on user's privileges and region.



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	Case Overview						Vigilance Periodic			
Case Creation Date 11/11/2021, 6:15 AM	Status Data Entry		Case Type Unsolicited	Case Category Spontaneous			in acti	on:		
Manufacturer Receipt Date 11/10/2021, 6:38 PM	MRD Justification		MRD Justification Descr	iption			During case	n processi	na usars	
Case Validity Valid Case	Invalid / Non-case Justification	0	Invalid Case Description				can mark c	•		
Case Serious?	Override Case Seriousness		Justification for overridi PdM Testing	ng Case Seriousness			Report type			
		Case Seriou	isness Criteria				automatica			
Non-Serious 0	Medically Significant	0	Requiring Intervention	C	used / Prolonged Hospitalization		aatomatica	my micraac	. as necaec	
Life Threatening	Results in Death	0	Disabling / Incapacitatin	ng 🐧 Ci	ongenital Anomaly / Birth Defect					
Medically confirmed Yes	Primary Reporter Country United States		Country Of Incidence United States		gregate Reporting Case Type ost Marketing - Spontaneous					
Date Archived	Archive Justification	Case	Archive Archive Justification Oth	ner						
		Report	Report Forms			C Q Search this list New				
		Templat		Report Form Type	Ingredients/Products	Last Modified by	Date Last Modified	Creator	Actions	
		8 PADER F	Report template_data_1	PADER	Wonder Drug Substance	US AR Supervisor User	2/22/2022	US AR Supervisor User	▼ (6)	
		9 PADER F	Report template_data	PADER	Wonder Drug Substance	US AR Supervisor User	2/11/2022	US AR Supervisor User	▼ Ø Pof	
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		12 COPY_O	F_PBRER Report template_1	1 PBRER	Wonder Drug, 200 mg, Coated tablet Wonder Drug Substance	US AR Supervisor User	1/31/2022	US AR Supervisor User	ョ Copy 亩 Delete	
		13 PBRER R	Report template_1	PBRER	Wonder Drug Substance	US AR Supervisor User	1/28/2022	US AR Supervisor User	□ Generate	
Report Form					Cancel Save					
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Enter Footer Text Include Meddra Version Used				PRODUCT INDIC			•			
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Simple selection of pr				PROTOCOL ID(S) Select/Edit Clear All						
and basic inclusion cr	 		Date Parameters —							
		— Cui	te type Exclude non-Significant Follow mulative Period —	v Up						
		Cumulati Jan 1,	ve Start Date 2022			27, 2022		首		
▼		Tabulatio	ns & Listings –			-				
— General Criteria —						-				
Include Unsponsored Study Cases			Exclude Unapprove	ed Cases						
Display Unblinded Information			Exclude Drug Not	Administered Cases						
— Clinical Trial —							Easy to sele	act the ref	erence	
Clinical Trial Datasheet for Reference Marketed Package Insert	•								CIEIICE	
Cumulative Summary Tabulation of S.	AEs from Clinical Trials ——					-	data sheet.			
— Post Marketing —						_				
Post-Marketing Datasheet for Reference										
Post-Marketing Datasneet for Reference										
Investigator Brochure	¥									
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Investigator Brochure						-				
Investigator Brachure Core Datasheet / Investigator Brachure Marketed Package Insert Other	Marketing Ex					- - -				
Investigator Brochure Core Datasheet Investigator Brochure Marketed Package Insert Other EMA Important Medical Event (IME) List	Marketing Ex									
Investigator Brochure Core Datasheet Investigator Brochure Marketed Package Insert Other	Marketing Ex									

