1. Reporter Details		☐Initial ☐Follow-up
Reporter Name:		E-mail:
Contact address:		Telephone number:
		Fax number:
Type:	☐ Physician (Specialty): _____	☐ Consumer or other non healthcare professional
	☐ Pharmacist	☐ Other (Specify) _____

If reporter is a consumer, have they informed their physician of the exposure? ☐ Yes ☐ No

Has the consumer provided permission to contact their healthcare professional? ☐ Yes ☐ No

If yes, please provide healthcare professional contact details:		
Name:	Type:	Telephone:
Address:		Email:

2. Patient Details			
Date of birth (Day/Month/Year)	Age Yrs/mo.	Height cm	Weight kg

3. Company Drug Section

	Name	Strength	Dose	Route	Indication	Treatment start date (day/month/year)	Treatment end date (day/month/year)	Lot	Expiry
1.									
2.									
3.									

4. Details of Adverse Event

Adverse Event	Start Date	Stop Date	Outcome
			☐ Recovered / Resolved ☐ Recovered / Resolved With Sequelae ☐ Recovering /Resolving ☐ Not Recovered /Not Resolved ☐ Fatal ☐ Unknown

5. Medical History

Medical History *(Enter all treatments below)*	▪ IBD History Specify Type Date of Diagnosis Therapies Received ▪ Malignancy Specify Type Date of Diagnosis ▪ Immune Deficiency Human Immunodeficiency Virus (+/-) If (+), Date of Diagnosis

	If (+), CD4 Count (at time of PML diagnosis) ▪ Ongoing graft-versus-host disease (Yes/No)
Prior Treatments for IBD:	▪ Long-term immunosupression (ie. greater than 8 weeks) (Yes/No) Include medications, dose, route, frequency, start/stop dates for each medication/treatment received.
Prior Treatments for Other Important Past Medical History Conditions:	

6. PML Disease
Signs and Symptoms of PML *(include onset date(s) for each sign and symptoms)*
Neurology Examinations *(include date examination was conducted and results of examination)*
Brain MRI / Brain Imaging Studies *(include date of MRI and MRI results, types and results of other brain imaging studies)*
Lumbar Puncture Results *(document all lumbar punctures, especially date of lumbar puncture of the first JCV DNA (+) cerebrospinal fluid (CSF) result)*
Brain Biopsy *(include date of brain biopsy, highlights of brain biopsy pathology report, evidence of JCV on immunohistochemistry or FISH staining)*

7. Labs			
	Date (day/month/year)	**Results**	**Normal Range**
White Blood Cell Count			
White Blood Cell Count Differential			
Hemoglobin			
Hematocrit			
Platelet Count			
Other			
JCV Antibody Status			

JCV DNA (non-CSF sources for JCV testing)			

8. PML Diagnosis and Treatment		
Date of PML Diagnosis (day/month/year) Date of Permanent Discontinuation of Teriflunomide Treatment (day/month/year)	Plasma Exchange (PLEX) / Immunoadsorption (IA) ☐ PLEX ☐ IA Dates of treatment: Number of cycles:	Other PML Treatments *(include type of treatment(s), dose, route, frequency, start/stop dates for each treatment received)*

9. Follow-Up
Any treatments for underlying disease post-PML diagnosis: ☐ Yes ☐ No If yes, specify:
PML Outcome: Event of PML continuing: ☐ Yes ☐ No Current clinical status of patient: Outcome of the event: ☐ Recovered / Resolved ☐ Recovered / Resolved With Sequelae ☐ Recovering /Resolving ☐ Not Recovered /Not Resolved ☐ Fatal ☐ Unknown If PML resulted in fatal outcome, provide date of death (day/month/year): Cause of death: Autopsy conducted (and report available): ☐ Yes ☐ No

10. Completed By		
Name:	Signature:	Date (day/month/year):