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	Event Causality
			☐ Recovered / Resolved ☐ Recovered / Resolved With Sequelae ☐ Recovering /Resolving ☐ Not Recovered /Not Resolved ☐ Fatal ☐ Unknown	☐ Related ☐ Not Related ☐ Unknown

5. Medical History		
Medical History	Diagnosis	Date

Medication History	Name	Dose	Indication	Treatment start date (day/month/year)	Treatment end date (day/month/year)

Prior Treatments for Other Important Past Medical History Conditions:

6. PML Disease

Expanded Disability Status Scale (EDSS) score (prior to symptoms and after symptom onset)

Signs and Symptoms of PML *(include onset date(s) for each sign and symptoms)*

	Result	Date (day/month/year)
Neurology Examinations		
Brain MRI / 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 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)	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)*
Diagnosis: ☐ Suspected ☐ Confirmed ☐ Indeterminate		
Date of Permanent Discontinuation of Teriflunomide Treatment (day/month/year)		

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):