61 data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for 2 conditions: 51 new disease-specific data elements for toxoplasmosis, and 10 new disease-specific data elements for congenital toxoplasmosis. Names, descriptions, value set codes (the answer list for coded data elements from CDC vocabulary server (PHIN VADS) which can be accessed at http://phinvads.cdc.gov), and justification for the addition of these new data elements are below:

Toxoplasmosis	
The impetus/urgency for CDC to add data elements for this condition	• A standardized surveillance case definition for toxoplasmosis was approved in 2023 by the Council of State and Territorial Epidemiologists (CSTE), providing a framework for consistent reporting and enhancing quality of toxoplasmosis data across states and jurisdictions. • Toxoplasmosis is a significant public health issue that can cause severe health complications in immunocompromised individuals, pregnant women, and their unborn children. • There has been growing awareness of the risks associated with toxoplasmosis, particularly in relation to food safety (e.g., undercooked meat) and environmental exposure (e.g., contaminated soil). Enhanced data collection can help identify risk factors and inform prevention strategies. • Adding data elements would improve surveillance capabilities, allowing for better tracking of cases, outbreaks, and trends over time. • Robust data is essential for developing evidence-based policies and guidelines related to the prevention and management of toxoplasmosis at local, state, and national levels. • As toxoplasmosis is a global concern with varying prevalence rates across different regions, improved data collection can contribute to international efforts in monitoring and controlling the disease.

Label/Short Name	**Description**	**Value Set Code**	**CDC Priority**
Date first received by Public Health Agency	Date first received by Public Health Agency	N/A	3
Previous Evidence of Toxoplasmosis	Does the patient have previous evidence of toxoplasmosis	PHVS_YesNoUnknown_CDC	1
Estimated Date of Delivery of the Pregnancy	If the patient is pregnant, estimated date of delivery of the pregnancy	N/A	2
Pregnancy Outcome	What was the outcome of the pregnancy?	TBD	2
Die within ≤ 7 days of life	If live born, did the infant die within ≤ 7 days of life?	PHVS_YesNoUnknown_CDC	2

Patient immunocompromised	At time of diagnosis, was the patient immunocompromised due to medical condition(s) or treatment	PHVS_YesNoUnknown_CDC	2
Immune compromising condition or treatment	If patient was immunocompromised, what was the associated condition or treatment	TBD	2
Case associated with at least one probable or confirmed case of active toxoplasmosis	Is this case associated with at least one probable or confirmed case of active toxoplasmosis?	PHVS_YesNoUnknown_CDC	2
linked case	case ID number for the linked case	N/A	2
Reason for testing	Reason for testing	TBD	2
Patient symptomatic	Was the patient symptomatic for toxoplasmosis?	PHVS_YesNoUnknown_CDC	1
Date of onset estimated	Is date of onset is estimated	PHVS_YesNoUnknown_CDC	2
Clinical manifestations	Clinical manifestations	TBD	1
Clinical manifestations Indicator	Clinical manifestations Indicator	PHVS_YesNoUnknown_CDC	1
Admitted to an intensive care unit	If Yes, was the patient ever admitted to an intensive care unit during that visit?	PHVS_YesNoUnknown_CDC	3
Did the patient die	Did the patient die	PHVS_YesNoUnknown_CDC	1
Death Related to Toxoplasmosis	If patient died, was death related to toxoplasmosis	PHVS_YesNoUnknown_CDC	1
Date of Death	If patient died, date of death?	N/A	2
Imaging type	Imaging type	TBD	3
Imaging date performed	Imaging date performed	TBD	3
Imaging Result	Imaging Result	TBD	3
Further classification	Further classification	TBD	3
Case is LTFU or not investigated further.	Check if case is LTFU or not investigated further.	PHVS_YesNoUnknown_CDC	3
Patient Receive Treatment	Did the patient receive treatment for toxoplasmosis	PHVS_YesNoUnknown_CDC	3

Medications administered	Medications administered	TBD	3
Patient travel out of their county, state, or country of residence	In the 30 days prior to illness onset or diagnosis (use earlier date) did the patient travel out of their county, state, or country of residence	PHVS_YesNoUnknown_CDC	2
International Travel	International Travel?	PHVS_YesNoUnknown_CDC	2
Domestic Travel	Domestic Travel?	PHVS_YesNoUnknown_CDC	2
Travel Country	Travel Country	TBD	2
Travel Arrival Date	Travel Arrival Date	N/A	2
Travel Departure Date	Travel Departure Date	N/A	2
Travel State or Territory	Travel State or Territory	PHVS_State_FIPS_5-2	2
Immigration Date	If patient born outside the US, when did the patient immigrate to the United States?	N/A	2
Patient consumed any meat or shellfish	In the 30 days prior to illness onset or diagnosis (use earlier date), did the patient consume any meat or shellfish?	PHVS_YesNoUnknown_CDC	2
Type of meat or shellfish	Type of meat or shellfish	TBD	2
Source of meat or shellfish	Source of meat or shellfish	TBD	2
Method of cooking or prepping meat or shellfish	Method of cooking or prepping meat or shellfish	TBD	2
Patient drank unpasteurized or raw milk	In the 30 days prior to illness onset or diagnosis, did the patient drink any unpasteurized or raw milk?	PHVS_YesNoUnknown_CDC	2
Patient’s drinking water source	In the 30 days prior to illness onset or diagnosis, what was the patient’s drinking water source(s)?	TBD	2
Patient have any contact with kittens, cats, or their feces	In the 30 days prior to illness onset or diagnosis, did the patient have any contact with	PHVS_YesNoUnknown_CDC	2

	kittens, cats, or their feces?		
Activities that led to the exposure	If Yes, what activities led to the exposure?	TBD	2
Patient work with soil	In the 30 days prior to illness onset or diagnosis, did the patient work with soil	PHVS_YesNoUnknown_CDC	2
Patient play in sand	In the 30 days prior to illness onset or diagnosis, did the patient play in sand	PHVS_YesNoUnknown_CDC	2
Patient received a transfusion of blood or blood products	In the 30 days prior to illness onset or diagnosis did the patient receive a transfusion of blood or blood products?	PHVS_YesNoUnknown_CDC	2
Infection transfusion associated	Was the patient's infection transfusion associated?	PHVS_YesNoUnknown_CDC	2
Type(s) of transfused blood products	If a transfused blood product was implicated in an investigation, specify which type(s) of product	TBD	2
Date(s) of transfusion	Date(s) of transfusion	N/A	2
Patient received an organ or tissue transplant(s)	In the 30 days prior to illness onset or diagnosis, did the patient receive an organ or tissue transplant(s)?	PHVS_YesNoUnknown_CDC	2
Infection transplant-related	Was the patient's infection transplant-related?	PHVS_YesNoUnknown_CDC	2
Organ or Tissue transplanted	what was the organ or tissue transplanted?	TBD	2
Date(s) of organ or tissue transplant	Date(s) of organ or tissue transplant	N/A	2

Congenital Toxoplasmosis	
The impetus/urgency for	• A standardized surveillance case definition for congenital toxoplasmosis

CDC to add data elements for this condition	was approved in 2023 by the Council of State and Territorial Epidemiologists (CSTE), providing a framework for consistent reporting and enhancing quality of congenital toxoplasmosis data across states and jurisdictions. • Congenital toxoplasmosis can lead to severe health issues in newborns, including neurological damage, vision problems, and other serious complications. • Enhanced data elements can improve surveillance systems, allowing for more accurate tracking of cases. Comprehensive data on congenital toxoplasmosis can help public health officials allocate resources more effectively, targeting areas with higher incidence rates or populations at greater risk. • Better data can inform prevention strategies and educational campaigns aimed at reducing the risk of infection during pregnancy, ultimately leading to better outcomes for mothers and infants. • Improved data collection can facilitate research into the epidemiology of congenital toxoplasmosis, helping to identify risk factors and potential interventions. • Robust data is essential for developing effective public health policies and guidelines related to screening, diagnosis, and treatment of congenital toxoplasmosis.

Label/Short Name	Description	Value Set Code	CDC Priority
Date first received by Public Health Agency	Date first received by Public Health Agency	N/A	3
Birthweight	Birthweight	N/A	3
Birthweight units	Birthweight units	TBD	3
Gestational age at diagnosis	Gestational age at diagnosis	N/A	2
Gestational age at delivery	Gestational age at delivery	N/A	2
Vital status	Vital status of patient at time of report	TBD	2
Date of death	If died, date of death	N/A	2
Clinical manifestations	Clinical manifestations (check all that apply)	TBD	1
Pregnant person toxoplasma infection status	Fetus or infant delivered to a pregnant person with evidence of Toxoplasma gondii infection or toxoplasmosis acquired or reactivated during current gestation or within 6 months	PHVS_YesNoUnknown_CDC	1

	prior to conception.		
Birth parents state Case ID	Gestational age at delivery	N/A	2