

Addressing an Emerging Safety Need: Neutropenia Among Clozapine Users

Sentinel Study Protocol

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The Sentinel System is sponsored by the [U.S. Food and Drug Administration \(FDA\)](#) to proactively monitor the safety of FDA-regulated medical products and complements other existing FDA safety surveillance capabilities. The Sentinel System is one piece of FDA's [Sentinel Initiative](#), a long-term, multi-faceted effort to develop a national electronic system. Sentinel Collaborators include Data and Academic Partners that provide access to healthcare data and ongoing scientific, technical, methodological, and organizational expertise. The Sentinel Operations Center is funded by the FDA through the Department of Health and Human Services (HHS) Task order 75F40124F19013.

History of Modifications

Version	Date	Modification	Author
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Study Team and Participating Sites

Sentinel Operations Center Study Team

The study team at the Sentinel Operations Center (SOC) will manage study operations and collaborate with the Innovation Center (IC) study team to accomplish the objectives described in this protocol.

Principal Investigator:	Judith C. Maro, PhD, MS
Epidemiologist:	Ashley I. Michnick, PharmD, PhD
Lead Research Analyst:	Andrew Simon, ScM
Research Assistant:	Anne Vasquez, MPH
Project Manager:	Maria Lewis, MPH
Program Manager:	Meighan Rogers Driscoll, MPH

Innovation Center Study Team

The study team at Mass General Brigham (MGB) within the IC will collaborate with SOC teams to accomplish objectives described in this protocol.

Principal Investigator:	Rishi Desai, MS, PhD
Lead Analyst:	Priyanka Anand, MBBS, MPH
Lead Programmer:	Joyce Lii, MS, MA
Informatician:	Bowen Gu, MS
Clinical Expert Consultant:	Philip Wang, MD, DrPH
Project Manager:	Haritha Pillai, MPH

Objectives

The primary objective of this study is to characterize the occurrence of neutropenia among clozapine users within a sample of patients with Medicare Fee-for-Service or Medicaid insurance coverage at a regional healthcare system in the Boston area.

Background and Rationale

Sentinel Response to Emerging Safety Needs

The Sentinel Initiative is a congressionally mandated program that requires the U.S. Food and Drug Administration (FDA) to collaborate with public, academic, and private entities to develop methods for obtaining access to disparate data sources and to validate means of linking and analyzing safety data from multiple sources.^{1,2} FDA has created a national electronic Active Risk Identification and Analysis (ARIA) system with at least 100 million individuals. ARIA fulfills the FDA's mandate (section 505(o)(3)(D)(i) of the Federal Food, Drug, and Cosmetic Act) to modernize safety surveillance by capitalizing on electronic healthcare data, advancing epidemiological methods, and expanding the FDA's capabilities of post-market surveillance for approved medical products. The Sentinel System also maintains the Real-World Evidence Medical Data Enterprise (RWE-DE) that builds a “modern system that would rely on the electronic medical records from about 10 million lives.”³ This initiative aligns with the 21st Century Cures Act (“Cures Act”)⁴ which promotes and strengthens the use of Real-World Evidence to support or satisfy post-approval study requirements.

The work described in this protocol supports the Sentinel System's capabilities to address an emerging safety need as identified by FDA's Office of Surveillance and Epidemiology leadership in support of the Center for Drug Evaluation and Research (CDER)'s mission to ensure that safe and effective drugs are available to improve the health of people in the United States. Because drug-related adverse events have the potential to broadly affect public health, there is often an urgency to take regulatory action to address drug safety issues.

Safety Need of Interest: Clozapine-Induced Neutropenia

Clozapine, the drug of interest in this study, is an antipsychotic used for serious and often treatment-resistant psychiatric disorders.⁵ Clozapine may cause severe neutropenia, a condition where there is a lower than normal number of neutrophils, a type of white blood cell, in the blood. Severe neutropenia can lead to serious infection and death. To minimize this risk, FDA instituted a Risk Evaluation and Mitigation Strategy (REMS) in September 2015,⁶ requiring weekly monitoring of absolute neutrophil count (ANC) for the first six months of clozapine treatment.

Leveraging the Sentinel System

This study supplements ongoing work within the ARIA system, which includes a complete characterization of clozapine users within the Sentinel Distributed Database (SDD) and a review of Sentinel Common Data Model (SCDM) records for neutropenic users.

Because neutropenia is most reliably detected in secondary health data using ANC laboratory results (as opposed to diagnoses⁷), this additional clinical information is crucial to assessing neutropenia among clozapine users. Prior work within ARIA has shown that the majority of clozapine users in the SDD have Medicare and/or Medicaid insurance coverage, but unfortunately, the Centers for Medicare & Medicaid Services (CMS) does not provide laboratory results.

Thus, this study will leverage Sentinel's RWE-DE to identify clozapine users in a dataset with clinical electronic medical record data from a local health system linked to administrative claims data from CMS and additionally provide a review of structured claims and unstructured clinical data for neutropenic users.

Study Design

Data Sources

This study will use a linked administrative claims-electronic medical record database from the Mass General Brigham (MGB) health system within the Sentinel RWE-DE. The MGB system is the largest healthcare system in the state of Massachusetts, consisting of two large academic and multiple specialty hospitals, and a large network of specialty practices, urgent care facilities, and outpatient clinics. The MGB team has worked with CMS to deterministically link 1.2 million individuals with electronic medical records (2000-2020) to national Medicare (2007-2022) and Medicaid claims (2000-2018). In addition to these administrative claims, the MGB team has populated clinical tables within the SCDM with structured medical records and curated free-text notes from all encounters occurring at MGB-affiliated facilities (except for notes from one mental health specialty hospital, which is not available due to privacy restrictions). The MGB team also leverages a curated clinical text metadata table and a Natural Language Processing (NLP)-assisted review tool^B to improve the efficiency of note review. Code lists used for this analysis can be found in Appendix A.

Included Patient Population

Patients aged 12 years or older in the MGB dataset with continuous enrollment in medical and drug coverage for at least six months prior to clozapine initiation (allowing for up to 45 days of gaps to account for administrative lapses) will be included in this study. The MGB dataset includes patients who have ever had a visit at an MGB facility and were able to be linked to administrative claims records from fee-for-service Medicare or Medicaid data. We will include data from January 1, 2010 through December 31, 2020 in this study.

Creating Clozapine Treatment Episodes (Exposure)

Clozapine initiation (new use) is defined as evidence of a clozapine prescription dispensing without evidence of a dispensing in the prior 30 days. Dispensings will be bridged together when separated by 30 days or less to create clozapine treatment episodes, and we will follow patients until the earliest of: end of the clozapine episode, six months, disenrollment, death, query end, or data end. If a patient has subsequent clozapine treatment episodes that meet the definition of new use described above, we will also include these subsequent episodes.

Identifying Neutropenia (Outcome)

We will assess neutropenia during the first six months of clozapine treatment episodes. Neutropenia will be defined as an ANC laboratory result of <1,500 neutrophils per microliter (μL). We will classify neutropenia into mild (1,000 to <1,500 neutrophils/ μL), moderate (500 to <1,000 neutrophils/ μL), and severe (<500 neutrophils/ μL) categories. Since this study period includes the ICD-10-era, and the validity of neutropenia diagnoses in this era has not been assessed, we will secondarily identify neutropenia using diagnosis codes. Diagnosis

codes are generally non-specific and cannot be classified by severity, except for a new ICD-10-CM code for agranulocytosis which will be classified as severe.⁹ Non-specific diagnosis codes will be included in the definition of neutropenia as a sensitivity analysis since the validity of these codes is already known to be low.⁷

Of note, neutropenia diagnoses may originate either at an MGB-affiliated facility or at a non-affiliated facility (if sourced from the linked administrative claims). ANC laboratory results originate at an MGB-affiliated facility since these data are not available from CMS.

Because we may identify multiple instances of neutropenia in the first six months of a clozapine treatment episode, we will identify a “defining neutropenic event” as the most severe instance of neutropenia. If an agranulocytosis diagnosis code is present along with a severe ANC laboratory result, the defining neutropenic event will be the earlier instance.

Sampling Method

Literature suggests that the incidence of any clozapine-associated neutropenia is 3-5%, while the incidence of serious clozapine-associated neutropenia is 0-2%.^{10,11} Since we have previously identified clozapine users in related studies using this data, we know that we will be able to review all identified cases of neutropenia. We will prioritize review of neutropenia cases identified with ANC laboratory results and the new ICD-10-CM code for agranulocytosis, followed by a review of the cases identified with only ICD-9-CM codes as time permits, since these codes have already been demonstrated to have low validity.⁷

Assessment of Neutropenia Among Clozapine Users (Analysis)

After constructing clozapine treatment episodes among a cohort of new users at MGB with Medicare or Medicaid insurance coverage, we will perform a review of structured EHRs and free-text notes for clozapine episodes with evidence of neutropenia in the first six months of treatment. Of note, because we expect sample sizes to be small and the patient population in this study may not be generalizable to all clozapine users, we will not perform any quantitative analyses based on the structured nor unstructured data review. Rather, we will focus on a narrative description of the neutropenic events, their pre-disposing factors, and their subsequent handling.

Structured Data Review

We will perform a review of structured data by outputting a line list of all SCDM records in the clozapine user's profile during their first six months of treatment (or through up to 30 days after the defining neutropenic event, whichever is later). We will create an abstraction form in REDCap¹² (see Appendix C for full abstraction form) to extract the following pieces of information from the structured data:

- Clozapine user demographics
 - Sex
 - Age
 - Race
 - Ethnicity
- Clozapine treatment episode characteristics
 - Regulatory period in which clozapine episode was identified (1/1/2010 - 9/30/2015 "Pre-REMS"; 10/1/2015 - 12/31/2019 "Post-REMS"; 1/1/2020 - 12/31/2022 "COVID-REMS")
 - Number of dispensings comprising the treatment episode
 - Total days supply comprising the treatment episode
 - Number of clozapine episodes identified in the query period
 - Whether clozapine had ever been dispensed prior to the treatment episode
 - Total follow-up time, including reason for censoring
- ANC monitoring patterns
 - Number of distinct dates in the first six months of the clozapine treatment episode on which an ANC laboratory result is identified
 - Number of distinct dates in the first six months of the clozapine treatment episode on which a claim for a procedure that includes ANC monitoring is identified
 - "ANC procedure-laboratory result correspondence," defined as the number of ANC laboratory results divided by the number of ANC procedures such that a clozapine episode with at least as many ANC laboratory results as ANC procedures will have a value $\geq 100\%$
 - Timing of ANC laboratory results relative to defining neutropenic event
- Neutropenia characteristics
 - Most severe category of neutropenia (mild, moderate, severe, unclassified)
 - Timing of most severe instance of neutropenia relative to clozapine initiation
 - Whether more than one ANC laboratory result was present on the same day as the most severe instance of neutropenia
 - Number of clozapine dispensings that occurred after the defining neutropenic event
 - Number and categorization of neutropenic events during the clozapine episode and before the defining neutropenic event

- Number and categorization of neutropenic events during the clozapine episode and after the defining neutropenic event
- Potential pre-disposing factors assessed in the [-30, -8] and [-7, -1] days prior to defining neutropenic event
 - Serious infection defined as an inpatient diagnosis of bacteremia, pneumonia, skin/soft tissue infection, gastrointestinal infection, acute osteomyelitis, acute pyelonephritis, or acute meningitis preceded in the seven days prior to admission by either an emergency department visit for a non-serious infection or an anti-infective dispensing ¹³
 - Chemotherapy
- Potential neutropenia follow-up care assessed in the [0,7] and [8, 30] days after the defining neutropenic event
 - Serious infection defined as an inpatient diagnosis of bacteremia, pneumonia, skin/soft tissue infection, gastrointestinal infection, acute osteomyelitis, acute pyelonephritis, or acute meningitis preceded in the seven days prior to admission by either an emergency department visit for a non-serious infection or an anti-infective dispensing ¹³
 - Anti-infective administration or dispensing
 - Filgrastim injection
 - Clozapine discontinuation (evidenced by lack of clozapine dispensings)

Free-Text Note Review

We will perform a review of free-text notes in addition to a review of the structured data to attempt to provide more clinical context to the defining neutropenic event. Of note, ANC laboratory results from MGB facilities are considered structured data and may not always be associated with unstructured data, such as free-text notes. Thus, we do not expect all clozapine episodes with a defining neutropenic event to necessarily have unstructured data for review.

We will begin the unstructured data review by extracting free-text notes for a period of 90 days prior through 180 days after the defining neutropenic event, noting that the free-text notes from one mental health specialty hospital are not available to protect patient privacy. Clozapine treatment episodes without any free-text notes within [-90, 180] days around the defining neutropenic event will not be further abstracted.

If free-text notes are available in that timeframe, we will review records within ± 7 days around the defining neutropenic event to determine whether there is any mention of the neutropenia. These clinical notes will be first prepared for abstraction using an NLP-assisted tool developed at MGB, which takes in a list of keywords related to clozapine and neutropenia and highlights relevant sections to increase review efficiency. The purpose of restricting the search for neutropenia mentions in free-text notes to a week timeframe around the defining neutropenic event is to ensure that abstraction only pertains to the neutropenic event that was identified from the SCDM.

If there are free-text notes with mention of neutropenia ± 7 days around the defining neutropenic event identified with diagnosis codes, we will proceed with free-text note data abstraction, including all free-text notes from clozapine initiation through a maximum of 30 days after the defining neutropenic event. For defining neutropenic events identified using ANC lab results, we will also conduct data abstraction from free-text notes, whenever they are available.

We will create an abstraction form in REDCap¹² (see Appendix C for full abstraction form) to extract the following pieces of information from the free-text notes:

- Background on clozapine use
 - Whether clozapine was being used to treat symptoms of schizophrenia or schizoaffective disorder, and if so, how well-controlled symptoms appeared to be
 - Whether any potential alternate causes for neutropenia were mentioned, and if so, which potential alternate cause
 - Whether clozapine plasma level was recorded, and if so, its results
 - Whether there was a discussion of historical clozapine plasma level measurements
 - Whether there was a discussion of adherence to REMS-mandated ANC monitoring
- Likelihood that neutropenia was clozapine-induced
 - Whether clozapine was mentioned as the suspected cause of the neutropenia
 - Whether there is mention of past episode(s) of neutropenia, and if so, if they were attributed to clozapine
- Neutropenia treatment
 - Whether clozapine discontinuation, dose reduction, or alternate therapy was considered and/or implemented as a result of the neutropenia
 - Whether a rationale was provided for clozapine discontinuation or lack thereof, and if so, what the rationale was
 - Whether the neutropenia appears to have been medically treated, and if so, how

Data Collection and Quality Assurance

Data Collection

We will develop an abstraction form to guide both structured data and free-text note review. We will use the REDCap platform¹² to generate the form and to store data. REDCap is a web-based platform that is Health Insurance Portability and Accountability Act (HIPAA)-compliant and the instance used by the IC study team will be hosted behind the MGB firewall, ensuring adequate data privacy and protection.

Data Management

The SOC will write and distribute SAS programs to the IC that will be used to identify the cohort of clozapine treatment episodes with neutropenic events and output SCDM line-lists for review. Additionally, SOC will maintain a secure distributed querying web-based portal to enable secure distribution of analytic queries and document storage. This portal will meet all required State and Federal security guidelines for health data (e.g., Federal Information Security Management Act [FISMA], Health Insurance Portability and Accountability Act of 1996), specifically FISMA compliant for FISMA security controls as specified in the National Institute of Standards and Technology (NIST) Special Publication 800-53 (NIST and Joint Task Force Transformation Initiative 2017).

After receiving and locally executing a standardized analytical program containing cohort identification and analytical parameters developed by the SOC using the Sentinel Routine Querying System,¹⁴ the IC team will perform all analysis locally, consistent with privacy-preserving distributed research methods and data use agreements.^{15,16}

Data will be analyzed using SAS 9.4.¹⁷ Analytic and reporting programs will leverage the latest available version of Sentinel's routine querying tools, including the Cohort Identification and Descriptive Analysis module of the Query Request Package,¹⁴ the Query Request Package Reporting Tool,¹⁸ and the Patient Episode Profile Retrieval Tool,¹⁹ supplemented with additional custom programming to meet the study objectives.

Quality Assurance

We will abide by Sentinel's rigorous evaluation for quality and consistency²⁰ for all components of this study that use data from the SCDM. This process assesses consistency with the Sentinel Common Data Model, evaluates adherence to data model requirements and definitions, examines logical relationships between data model tables, and reviews trends in medical and pharmacy services.

Ethical Considerations

This Sentinel System study is a public health surveillance activity conducted under the authority of the Food and Drug Administration and, accordingly, is not subject to Institutional Review Board oversight.²¹

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Appendices

Appendix A. Code Lists

Table A1. List of Generic and Brand Names of Medical Products Used to Define Exposures in this Request

Generic Name	Brand Name
Clozapine	
clozapine	CLOZAPINE
clozapine	Clozapine
clozapine	Clozaril
clozapine	FAZACLO
clozapine	FazaClo
clozapine	VERSACLOZ
clozapine	Clozaril
clozapine	FazaClo
clozapine	Versacloz
clozapine	clozapine

Table A2. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and ICD-10-CM Diagnosis Codes; and Healthcare Common Procedure Coding System (HCPCS), Level II, and Current Procedural Terminology, Fourth Edition (CPT-4) and Revenue (REV) Procedures Codes; and Logical Observation Identifiers and Names Codes (LOINC) Laboratory Codes Used to Define Outcomes in this Request

Code	Description	Code Category	Code Type
Neutropenia			
288.00	Neutropenia, Unspecified	Diagnosis	ICD-9-CM
288.09	Other Neutropenia	Diagnosis	ICD-9-CM
D70.2	Other Drug-Induced Agranulocytosis	Diagnosis	ICD-10-CM
D70.8	Other Neutropenia	Diagnosis	ICD-10-CM
D70.9	Neutropenia, Unspecified	Diagnosis	ICD-10-CM
Absolute Neutrophil Count (ANC)			
0305	Laboratory-Hematology	Procedure	REV
80050	General health panel	Procedure	CPT-4
80055	Obstetric panel	Procedure	CPT-4
85004	Blood count; automated differential WBC count	Procedure	CPT-4

Code	Description	Code Category	Code Type
85007	Blood count; blood smear, microscopic examination with manual differential WBC count	Procedure	CPT-4
85008	Blood count; blood smear, microscopic examination without manual differential WBC count	Procedure	CPT-4
85009	Blood count; manual differential WBC count, buffy coat	Procedure	CPT-4
85025	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count	Procedure	CPT-4
85027	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)	Procedure	CPT-4
85032	Blood count; manual cell count (erythrocyte, leukocyte, or platelet) each	Procedure	CPT-4
85048	Blood count; leukocyte (WBC), automated	Procedure	CPT-4
G0306	Complete CBC, automated (Hgb, HCT, RBC, WBC, without platelet count) and automated WBC differential count	Procedure	HCPCS
G0307	Complete CBC, automated (Hgb, HCT, RBC, WBC; without platelet count)	Procedure	HCPCS
752-6	Deprecated Neutrophils [# /volume] in Blood by Automated count	Laboratory	LOINC
26499-4	Neutrophils [# /volume] in Blood	Laboratory	LOINC
751-8	Neutrophils [# /volume] in Blood by Automated count	Laboratory	LOINC
753-4	Neutrophils [# /volume] in Blood by Manual count	Laboratory	LOINC

Table A3. List of SOC-Defined (SOC) Laboratory Codes Used to Define Outcomes in this Request

Code	Description	Code Category	Code Type	Specimen Source	Patient Location	Result Unit*	Result
Neutropenia							
ANC	Any neutropenia	Laboratory	SOC	Blood, Unknown, Missing	Emergency, Home, Inpatient, Outpatient, Unknown	K/ μ L	(0, 1.5)
ANC	Mild neutropenia	Laboratory	SOC	Blood, Unknown, Missing	Emergency, Home, Inpatient, Outpatient, Unknown	K/ μ L	[1.0, 1.5)
ANC	Moderate neutropenia	Laboratory	SOC	Blood, Unknown, Missing	Emergency, Home, Inpatient, Outpatient, Unknown	K/ μ L	[0.5, 1.0)
ANC	Severe neutropenia	Laboratory	SOC	Blood, Unknown, Missing	Emergency, Home, Inpatient, Outpatient, Unknown	K/ μ L	<0.5

*K = 1,000 cells

Appendix B. Standard Operating Procedure

Document B1. Standard Operating Procedure (click image for PDF)

Standard Operating Procedure: Medical Record Retrieval Emerging Needs

Department of Population Medicine
Harvard Medical School / Harvard Pilgrim Health Care Institute

401 Park Drive
Suite 401 east
Boston, MA 02215

July 30, 2024

- 1 -

Document B2. Appendix A of Standard Operating Procedure (click image for PDF)

7/30/24, 11:48 AM Closeup: PCPI and Medical Record Review / RCD/Op

Project Name: Project Setup | Data Designer: Data Dictionary | Collected

Codebook

Data Dictionary Codebook 07/30/2024 3:45pm

ID	Variable / Field Name	Field Label	Field Attributes (Type, Validation, Default, Calculations, etc.)
Instrument: Abstraction Information (Click to expand)			
1	abstract_record_id	Abstraction Record ID <small>Field that is automatically assigned based on the order in which a patient's abstracts are abstracted. It is NOT visible in the PCPI software or within the...</small>	text, identifier
2	pcpi_request_id	PCPI Request ID	text, Required Field Annotation: @PCPI_REQUEST_ID
3	abstract_name	Abstraction Name	drop-down (no search), Required <ul style="list-style-type: none"> 1 Jay Rifkin 2 Maria Lora 3 Aron Marcus 4 Jeff Ware 5 Hans Weidner 6 Sara Heston 7 Anthony Schmitt 8 Andrew Simon 9 Priscilla Arnold 10 Other (Specify)
4	abstract_date	Date of PCPI record abstraction	text (datetime, yyyy, mm/dd) Field Annotation: @PCPI
5	abstraction_information_complete	Record Number (not shown) Complete	drop-down <ul style="list-style-type: none"> 0 Incomplete 1 Complete 2 Complete
Instrument: Elixhauser Characteristics (Click to expand)			
6	icd9_icd10	Specify case information	descriptive
7	icd9_icd10	ICD9-ICD10 <small>ICD9-ICD10: If the "ICD9" output to the unique PCPI/PCPI/PCPI combination you will be abstracting for all conditions listed.</small>	descriptive
8	pcpi_request	Data Partner in which record was identified <small>pcpi_request</small>	drop-down (no search) <ul style="list-style-type: none"> 1 ICD9 2 ICD10 3 ICD9 4 ICD10 5 ICD9 6 ICD10 7 ICD9 8 ICD10 9 ICD9 10 ICD10

https://www.sentinelstudy.com/PCPI/medicalrecordreview_v11.3.4/Design/PCPI_dictionary_codebook.php?tab=PCPI 1/20

Appendix C. Abstraction Forms

Document C1. Abstraction Forms (click image for PDF)

Note: This is the same PDF as Appendix A of the SOP listed in Appendix B above.

10/26/24, 11:48 AM Complete PDRs and Medical Record Review | RCD/Op

Project Name | Project Group | Data Designer | Data Dictionary | Codebook

Codebook

Data Dictionary Codebook 03/26/2024 5:05am

[Close all windows](#)

ID	Variable / Field Name	Field Label	Field Attributes (Field Type, Validation, Checks, Calculations, etc.)
Abstraction Information Subtraction_Information			
1	abstract_record_id	Abstraction Record ID	Field Attributes (Field Type, Validation, Checks, Calculations, etc.)
2	PHR_request_id	PHR Request ID	Field Attributes (Field Type, Validation, Checks, Calculations, etc.)
3	abstract_name	Abstraction Name	Field Attributes (Field Type, Validation, Checks, Calculations, etc.) Required Field Attributes (Field Type, Validation, Checks, Calculations, etc.) Selection (Dropdown) <ul style="list-style-type: none"> 1. All Records 2. Active Leads 3. Active Member 4. Daily Ware 5. Home Delivery 6. Care Medication 7. Family Medication 8. Member Medication 9. Program Member 10. Other (Specify)
4	abstract_date	Date of PHR record abstraction	Field Attributes (Field Type, Validation, Checks, Calculations, etc.)
5	abstraction_information_complete	Member Name: First Initial Complete	Field Attributes (Field Type, Validation, Checks, Calculations, etc.) Selection <ul style="list-style-type: none"> 1. Incomplete 2. Complete
Episode Characteristics Episode_Characteristics			
6	line_up	Episode Line Information	Field Attributes (Field Type, Validation, Checks, Calculations, etc.)
7	line_up_order	Order Number for the "line up" output to the table Particular/episode combination you will be abstracting for all conditions below	Field Attributes (Field Type, Validation, Checks, Calculations, etc.)
8	PHR_request	Data Partner in which record was identified	Field Attributes (Field Type, Validation, Checks, Calculations, etc.) Selection (Dropdown) <ul style="list-style-type: none"> 1. ICDIC 2. ICDIC-IP 3. ICDIC 4. ICDIC 5. ICDIC 6. ICDIC 7. ICDIC 8. ICDIC 9. ICDIC

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