TE AHO O TE KAHU CANCER CONTROL AGENCY

hiso Health Information Standards Organisation PAEREWA PĀRONGO HAUORA

ACT-NOW DATA STANDARD

HISO 10095:2022

Published XX 2022

New Zealand Government

MINISTRY OF HEALTH MANATŪ HAUORA

Contributors

The ACT-NOW (Anti-Cancer Therapy – Nationally Organised Workstreams) data standard was developed by the ACT-NOW Data Specification Working Group (DWG) as listed below.

Chairs: Dr Laird Cameron, Dr Jason Gurney
Project Manager: Alexander Dunn

- Dr Laird Cameron, Medical Oncologist, Auckland DHB and Canopy Cancer Care
- Dr Jason Gurney, Senior Research Fellow and Director, Cancer and Chronic Conditions (C3) Research Group
- Dr Myra Ruka, Clinical Lead Equity, Te Aho o Te Kahu and Advanced Haematology Registrar at Waikato Hospital
- Dr Christopher Jackson, Medical Oncologist, Southern DHB and Mercy Cancer Care
- Dr John Fountain, Manager, Data Monitoring and Reporting, Te Aho o Te Kahu
- Dr Humphrey Pullon, Haematologist, Waikato
- Dr Michelle Vaughan, Medical Oncologist, CDHB, St George's Cancer Care
- Dr Clinton Lewis, Haematologist, ADHB
- Laura Moughan, Pharmacist, Counties Manukau DHB
- Dr Shaun Costello, Radiation Oncologist, Southern Blood and Cancer Service Dunedin Hospital
- Janette Ngaheu, Haem Nursing / Programme Manager Clinical Equity – Waikato
- Simon Pointer, National Pharmacist, Treatment Quality and Standardisation, Te Aho o Te Kahu
- Alexander Dunn, Project Manager, Data Monitoring and Reporting, Te Aho o Te Kahu
- Kieron Mottley, Business Analyst, Data Monitoring and Reporting, Te Aho o Te Kahu

Te Aho o Te Kahu also undertook significant consultation with cancer health professionals and subject matter experts across the sector and acknowledges the many people and organisations who contributed to the publication of this standard.

Citation: Te Aho o Te Kahu. 2022. *HISO 10095:2022 ACT-NOW Data Standards.* Wellington: Te Aho o Te Kahu.

Published in XX 2022 by Te Aho o Te Kahu, the Cancer Control Agency
PO Box 5013, Wellington 6140, New Zealand

ISBN XXX-X-XX-XXXXXX-X (online)
HP XX XXXX

TE AHO O TE KAHU CANCER CONTROL AGENCY

This document is available at **teaho.govt.nz** and **health.govt.nz**

CONTENTS

1 INTRODUCTION

Te Aho o Te Kahu, the Cancer Control Agency is an independent departmental agency that was established to lead and unite efforts to deliver better cancer outcomes for Aotearoa. Te Aho o Te Kahu is responsible for developing and publishing cancer-specific data standards.

The **New Zealand Cancer Action Plan | Te Mahere mō te Mate Pukupuku o Aotearoa 2019-2029** provides a pathway to improve cancer outcomes for all New Zealanders with the objectives of building a system that delivers consistent and modern cancer care, equitable cancer outcomes, fewer cancers and better cancer survival, supportive care and end of life care.

The Anti-Cancer Therapy – Nationally Organised Workstreams (ACT-NOW) programme was launched in 2018 with the aim to develop a detailed database of information on patients receiving systemic anti-cancer therapy (SACT) across New Zealand. ACT-NOW engages with the medical oncology, haematology, pharmacist and nursing communities to identify and reduce variation, enhance equity of access and support resource planning.

ACT-NOW is a key deliverable identified in Te Aho's New Zealand Cancer Action Plan 2019-2029, with guiding principles that include:

1. Identify and understand key equity issues that exist within systemic therapy and that apply to most or all cancer types (for example, equity of access), and how the collection of specific data could support progress against resolving such issues.
2. Focus on the key issues that are relevant across systemic therapy, irrespective of cancer type.
3. Focus on data collected through oncology e-prescribing systems to help guide a pragmatic system with a high probability of successful implementation. This also means avoiding the shoehorning of new data into these systems where it would be more appropriate to collect elsewhere and/or through different Te Aho workstreams.
4. Have key outcome measures such as survival, treatment utility, etc, in scope.

The initial phase of this programme includes the development of national regimen definitions to create a solid foundation for the subsequent capture of nationally comparable data. The system for the development, maintenance and publication of regimen definitions is known as the SACT Regimen Library system (SRL) and was launched in February 2021.

The final phase includes development of this ACT-NOW data standard, which will support the establishment of a new systemic therapy national data collection and suite of analytics to guide improvements in equity, clinical quality and resource utilisation.

This document identifies and describes the data elements that should be captured from provider electronic systems and submitted into a national collection when prescribing and treating people living with cancer using systemic anti-cancer therapy. The standard was developed by the ACT-NOW Data Specification Working Group (DWG), guided by ACT-NOW principles of driving equity, clinical quality and efficiency within the context of adult medical oncology and malignant haematology.

The membership of the DWG includes representatives from medical oncology, haematology, oncology pharmacy, oncology nursing, research and equity reporting specialists. DWG's role is to develop and endorse the ACT-NOW data specification; the set of agreed and prioritised data requirements that are relevant to most/all cancer streams across medical oncology and malignant haematology. DWG would endure beyond this to provide ongoing guidance to the Medical Oncology Working Group (MOWG) or the Haematology Working Group (HWG) on any enhancements or refinements to the specification and on the interpretation of collected data.

1.1 Purpose

This document identifies and describes the data elements that should be captured from provider electronic systems and submitted into a national collection when prescribing and treating people living with cancer using systemic anti-cancer therapy. SACT refers to all anti-cancer drug treatments. This includes chemotherapy, targeted therapies, hormones and other drug therapies.

The standard aims to support Te Aho o Te Kahu and the Ministry of Health's vision to accelerate the shift to a fully interoperable digital health ecosystem. The Ministry of Health has developed an **Interoperability Roadmap** to support a modern, digitally enabled and data-driven health and disability system to improve equity and pae ora (healthy futures). An interoperable digital health ecosystem relies on the national adoption of data standards and collaboration across the health sector.

Te Aho o Te Kahu, in partnership with the Ministry of Health and health sector, will ensure the standard is reviewed and updated as required through the HISO processes.

1.2 Scope

This document covers data captured by the systemic therapy care team as part of the standard patient treatment planning, delivery and monitoring. It includes data elements that are relevant for adult solid or haematological cancers. The standard aims to leverage the structured data that already exists within oncology e-prescribing systems and therefore should not require significant additional data recording by clinical teams.

The standard does not cover:

- Adolescent and young adult cancer patients (AYA)
- Non-malignant bloods
- Clinical trials
- Patients that are not commencing systemic therapy
- Technical specification requirements for implementation, such as creating the data elements in a physical database system
- Capturing clinician details

1.3 Definitions

The following special terms are used in this document.

Term	Definition
AJCC	The American Joint Committee on Cancer (AJCC) develops evidence-based anatomic staging that supports clinicians in understanding and treatment cancer patients
DWG	ACT-NOW Data Specification Working Group
ECOG status	The Eastern Cooperative Oncology Group (ECOG) score, also called the WHO or Zubrod score, is a measure of cancer patients' general wellbeing. The score runs from 0 to 5, with 0 denoting perfect health and 5 death. The measure is used to help assess a patient's ability to cope with different treatment protocols such as chemotherapy.
HISO	The Health Information Standards Organisation is kaitiaki and the governing body for health information standards in New Zealand. HISO provides technical leadership and expert advice to the Ministry of Health and other health agencies on the development and adoption of health information standards.
HWG	Haematology Working Group
ICD-10-AM	The International Statistical Classification of Diseases and Related Health Problems version 10 – Australian Modification. ICD-10 is a health care classification system, providing a system of diagnostic codes for classifying diseases, including nuanced classifications of a variety of signs, symptoms, abnormal findings, complaints, social circumstances and external causes of injury or disease.
ICD-O	The International Classification of Diseases for Oncology (ICD-O) is a domain-specific extension of the International Statistical Classification of Diseases and Related Health Problems for tumour diseases. This classification is widely used by cancer registries to capture the morphology of a tumour.
Lead clinician	The clinician who assumes primary responsibility for the patient (subject to change as required).
MOWG	Medical Oncology Working Group
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms is a systematic, computer-processable collection of medical terms that provide definitions and synonyms that cover anatomy, diseases, findings, procedures, microorganisms, substances and so on. It is a consistent way to store, retrieve and aggregate medical data across specialties and sites of care.
Tumour group or stream	A group of similar or related cancers, usually categorised according to the bodily system or organ they are associated with (for example, bowel, gynaecological, breast).

1.4 Legislation and regulations

The following legislation and regulations are relevant to this standard:

- Health Information Privacy Code 2020

- Health Practitioners Competence Assurance Act 2003
- Privacy Act 2020
- Public Records Act 2005
- Health (Retention of Health Information) Regulations 1996.
- Medicines Act 1981 and Medicines Regulations 1984.

1.5 Te Tiriti o Waitangi and achieving equity

Te Aho o Te Kahu recognises the central importance of its Te Tiriti o Waitangi obligations, including working in partnership with Māori with a clear focus on achieving equity for Māori in terms of cancer outcomes. A critical factor in meeting Te Tiriti obligations and achieving equity objectives includes forming key relationships to inform the scope and development of this standard.

DWG includes Māori researcher/equity reporting specialist co-chair and haematologist members who are also members of the Hei Āhuru Mōwai Māori Cancer Leadership Aotearoa. This group is working together with Te Aho o Te Kahu on work to help reduce inequities for Māori across the cancer continuum. DWG also includes Waikato DHB's Programme Manager, Clinical Equity. Also consulted for this standard is He Ara Tāngata, Te Aho o Te Kahu's Consumer Reference Group to provide the voices of people living with cancer, and their whānau.

A primary focus for the DWG is to understand the key known or potential equity issues that exist within systemic therapy access, provision, and outcomes, and to develop a data standard that will support improvements to these. By enabling data capture that would allow for a deeper understanding of the nature and extent of equity issues, more targeted and effective strategies for addressing these inequities may be developed. This will include specific consideration of how data could achieve improved outcomes or equity for Māori.

With consistent data standards for cancer across the health sector, high-quality data can be used to monitor and audit patient pathways locally, regionally and nationally to support the equitable delivery of care across the pathway and improve cancer outcomes. To achieve this the ACT-NOW standard aims to identify the data required to measure and monitor the following to determine inequity of access to systemic therapy:

- access to systemic treatment
- timing of access (relative to diagnosis)
- types of medicines being accessed (best practice care)
- location of treatment relative to residence (patient mobility)
- all of the above, by stage of disease as acted on by clinician(s)
- all of the above, including privately funded care (to complete the picture of access equity)

1.6 Related specifications

The following documents have been used to develop or are referenced in this standard.

- **New Zealand Cancer Health Information Strategy**. Wellington: Ministry of Health
- **New Zealand Cancer Plan: Better, faster cancer care 2015–2018**. Wellington: Ministry of Health
- **New Zealand Cancer Action Plan 2019–2029 – Te Mahere mō te Mate Pukupuku o Aotearoa 2019–2029.** Revised January 2020. Wellington: Ministry of Health
- **HISO 10080 Systemic Anti-Cancer Therapy Regimen Data Standard.** In development.
- **HISO 10013:2015 HL7 Standards Endorsement**
- **HISO 10038.0:2017 Preface to the Cancer Data Standards**
- **HISO 10038.1:2011 Interim National Cancer Core Data Definitions Standard**
- **HISO 10038.3:2011 Interim National Cancer Core Data Standard**
- **HISO 10042 Medication Charting and Medicine Reconciliation Standards**
- **HISO 10045 Health Provider Identity Standard (draft standard available from standards@health.govt.nz)**
- **HISO 10046 Consumer Health Identity Standard**
- **HISO 10063:2017 GS1 Standards Endorsement**
- **HISO 10083:2020 Interoperability Roadmap**
- **Ministry of Health's Clinical Coding System code table**
- **Overall Treatment Utility.** The University of Edinburgh[1]
- **ISO/IEC 10646:2017 Information technology – Universal Coded Character Set (UCS)**

1.7 SNOMED CT

Coded data elements in ACT-NOW regimens use by default the SNOMED CT terminology for clinical information. The concepts making up each value domain are denoted by either the preferred term or a clinically agreed term and are linked to entries in the **SNOMED CT browser** (use Chrome to access this link). The SNOMED CT concept identifier (SCTID) can be viewed by hovering over the link.

Some data elements are restricted to a definite set of SNOMED CT concepts, while others are more open-ended and allow the user to select from a wider set of concepts, usually within a certain hierarchy or sub-hierarchy for example, the set of all disease concepts.

When new values need to be added to the value set collection, these principles apply:

- Where a suitable SNOMED CT concept exists in the SNOMED CT International Edition it will be used
- If a suitable concept in the SNOMED CT International Edition does not exist, a new concept will be created in the SNOMED CT New Zealand Extension.

[1] Creative Commons Attribution-ShareAlike CC BY-SA 4.0.

Systems should display the SNOMED preferred or clinically agreed term and capture the SNOMED concept identifier accordingly. See the **SNOMED CT Search and Data Entry Guide** for a guide to building a user-friendly search across the terminology.

The latest **SNOMED CT New Zealand Edition**, incorporating the SNOMED CT International Edition and released in April and October every year, is the standard distribution. SNOMED CT is free to use in New Zealand and easy to implement. Download and install each release from the **Member Licensing and Distribution Service** or integrate your software with the **SNOMED CT terminology service** provided by the Ministry of Health.

1.8 Character sets

Text data elements must accommodate macrons for te reo Māori and diacritic characters for other commonly used languages. By default, this means using the Unicode Basic Latin, Latin-1 Supplement and Latin Extended A character sets.

ISO/IEC 10646:2017 Information technology – Universal Coded Character Set (UCS) is the recognised standard. UTF-8 is the recommended character encoding.

1.9 Medicine concept specification

This standard specifies medicines using the New Zealand Medicines Terminology (NZMT) Medicinal Product (MP) concept SCTID and Tall Man lettering[2] preferred term.

Where the MP concept models a medicine that either:

- meets the requirements of the Health Quality & Safety Commission (HQSC) Medication Safety Expert Advisory Group's Specify Brand Advice Guidance or
- the working group has objective evidence that available presentations of the medicine are not interchangeable in oncology practice.

The human readable format displayed to users in software systems will be «MP preferred term» «(Brand Name)».

[2] Tall Man lettering is an error–prevention strategy to reduce the risk of look-alike and sound-alike medicine name confusion and errors. It uses selective capitalisation to make similar looking medicine names easier to differentiate.

1.10 Data element template

Data element specifications in this standard conform to the requirements of **ISO/IEC 11179 Information Technology – Metadata Registries (MDR)**.[3]

Definition	A statement that expresses the essential nature of the data element and its differentiation from other elements in the data set.		
Source standards	Established data definitions or guidelines relating to the data element.		
Data type	Alphabetic (A) Date Date/time Numeric (N) Alphanumeric (X) Boolean	**Representational class**	Code, free text, value or identifier. For date and time data types, use full date or partial date.
Field size	Maximum number of characters	**Representational layout**	The formatted arrangement of characters in alphanumeric elements, for example: • X(50) for a 50-character alphanumeric string • NNN for a 3-digit number • NNAAAA for a formatted alphanumeric identifier.
Value domain	The named, enumerated or described set of valid values or codes that are acceptable for the data element. Each coded data element has a specified code set.		
Obligation	Indicates if the data element is mandatory, conditional or optional. **Mandatory** means the data element is required unless an exception process is followed. **Conditional** means the data element is required based on another data element. **Optional** means that the data element is available but is not obligatory.		
Guide for use	Additional guidance to inform the use of the data element.		
Verification rules	Quality control mechanisms that preclude invalid values.		

[3] See **https://standards.iso.org/ittf/PubliclyAvailableStandards/index.html**

2 DATA ELEMENTS

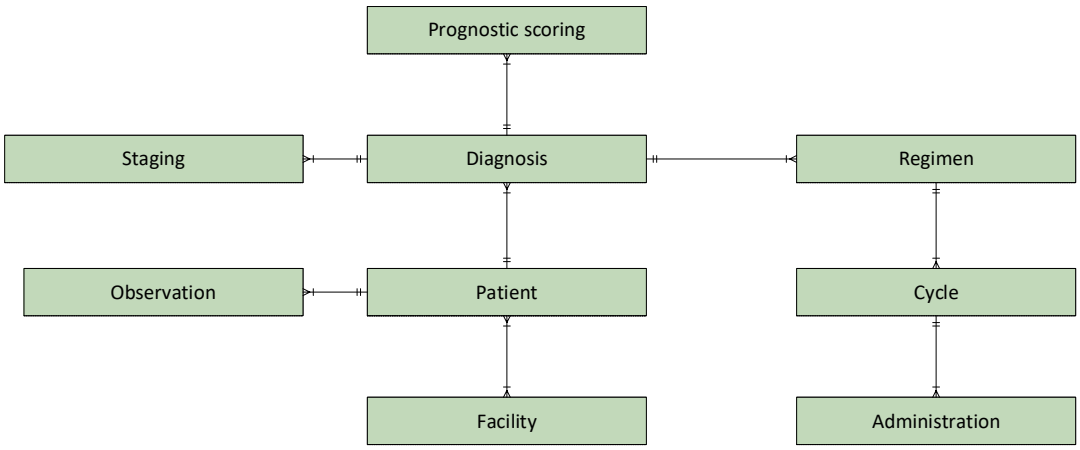
This section describes the set of core minimum data to be captured to support the recording of anti-cancer drug treatment.

Any electronic prescribing technical solution must be able to capture data for multiple treatment plans based on multiple diagnoses and assessments for the same person.

Each diagnosis must have one or more regimens. Each regimen must have one or more cycles which must have one or more administrations.

Figure 1 gives an overview of these relationships. The subsections that follow provide more detail on the data elements.

Figure 1: Conceptual model



2.1 Facility

Information relating to the health provider.

2.1.1 Facility ID

Definition	The unique identifier for the facility that is providing services associated with the patient's visit. The facility where the treatment is being delivered.		
Source standards	HISO 10045 Health Provider Identity Standard (draft standard available from **standards@health.govt.nz**).		
Data type	Alphanumeric	**Representational class**	Identifier
Field size	8	**Representational layout**	FXXNNN-C
Value domain	A valid HPI Facility ID		
Obligation	Mandatory		
Guide for use	The facility identifier is assigned by the HPI system when the facility record in the HPI is created. • It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • Should be automatically populated via integration between clinical systems. • F is a constant prefix – all facility identification numbers start with 'F'. • X is either an alphabetic or numeric. • N is a number. • C is the check digit established using the Modulus 11 system.		
Verification rules	A valid HPI FAC identifier.		

2.2 Patient

Information relating to the patient.

2.2.1 Patient details

The format for the following list of patient details is sourced directly from the **HISO 10046 Consumer Health Identity Standard.** Please use this standard for full definitions and format of these items.

Data elements	
National Health Index (NHI) number	Contact details
Given name	Street address/address line 1
Family name (surname)	Additional street address/address line 2

Data elements	
Date of birth	Suburb/address line 3
Ethnicity (1–6)*	Town or city/address line 4
Gender**	Postcode
Sex***	Domicile code

* See **HISO 10001:2017 Ethnicity Data Protocols** for the collection and recording of ethnicity data.

** Gender is self-identified (personal preference) and is captured in the patient's NHI record.

*** Sex is assigned genetically and is important when determining treatment; therefore, it is a mandatory field. See **HISO 10038.3 Interim National Cancer Core Data Definitions Standard** for a definition of this data element.

2.3 Diagnosis

Information relating to the patient diagnosis.

2.3.1 Date of diagnosis

Collecting the date of diagnosis is critical to assess timeliness of treatment and is not always captured within the NZ Cancer Registry.

Definition	The date of the primary diagnosis of cancer for which the patient is receiving systemic therapy.		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Mandatory		

Guide for use	Proposed date hierarchy Medical Oncology: 1. Date of first (not necessarily definitive procedure) Histology OR Cytology specimen collected. 2. Date Radiology used to make diagnosis was performed 3. Date Tumour markers/bloods taken. 4. Date of Clinical diagnosis. Haematology: 1. Cytology/Histology (for example, bone marrow aspirate or peripheral blood in acute leukaemias, biopsy in lymphomas, biopsy needed in myeloma to confirm diagnosis). 2. Flow cytometry (this is definitely diagnostic for conditions like CLL, and some other low grade B- and T- cell LPDs, sometimes confirms subtype of acute leukaemia). 3. Cytogenetics (this includes FISH) and Molecular (for example, chronic phase CML, JAK+ MPN).
Verification rules	A valid date that is less than or equal to the current date.

2.3.2 Primary cancer type

The primary cancer type is key to describing the diagnosis for which treatment is being prescribed, and for contextualising the treatment itself.

Definition	The primary cancer type of the diagnosis being treated.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA Note: A SNOMED CT NZ Edition reference set is under development for this element.		
Obligation	Mandatory		
Guide for use	• It is recommended this data be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems. • This must be accompanied with details of the clinical term and the clinical coding system used.		
Verification rules	Must be an active SNOMED CT concept.		

2.3.3 Histology

Histology information is key to describing the diagnosis for which treatment is being prescribed, and for contextualising the treatment itself.

Definition	The histologic type of the cancer being treated.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA Note: A SNOMED CT NZ Edition reference set is under development for this element.		
Obligation	Mandatory		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems. • This must be accompanied with details of the clinical term and the clinical coding system used.		
Verification rules	Must be an active SNOMED CT concept.		

2.3.4 Laterality

This information is useful for understanding the treatment being provided to a patient receiving chemoradiation.

Definition	Laterality describes which side of a paired organ is the origin of the primary cancer being treated.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain			

Clinical term	SCTID
Left	TBA
Right	TBA
Bilateral	TBA
Unknown	TBA
Not Applicable	TBA

Obligation	Optional
Guide for use	-
Verification rules	Must be an active SNOMED CT concept.

2.3.5 Grading system

The grading system indicates which grading system is being applied.

Definition	The grading system used to grade the cancer.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain			

Clinical term	SCTID
TBA	TBA
TBA	TBA
TBA	TBA
TBA	TBA
TBA	TBA

Obligation	Conditional; mandatory if **2.3.6 Grade** is provided.
Guide for use	• This data should be automatically populated via integration between clinical systems. • Different grading systems may be applied to different tumour types.
Verification rules	Must be an active SNOMED CT concept.

2.3.6 Grade

The grade of the cancer is key to describing the diagnosis for which treatment is being prescribed, and for contextualising the treatment itself.

Definition	The grade of the cancer being treated.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain			

Clinical term	SCTID
TBA	TBA
TBA	TBA
TBA	TBA
TBA	TBA
TBA	TBA

Obligation	Optional
Guide for use	TBA - Cancer type rules for use.
Verification rules	Must be an active SNOMED CT concept.

2.3.7 Grading system version

The version of the grading system used is key for futureproofing the data collection as grading systems may change over time.

Definition	Version of the grading system used to grade the cancer being treated.		
Source standards	-		
Data type	TBA	**Representational class**	TBA
Field size	TBA	**Representational layout**	TBA
Value domain	TBA		
Obligation	Conditional; mandatory if **2.3.6 Grade** is captured.		
Guide for use	• The data element must be provided to prescribe systemic anti-cancer therapy if a tumour grade is provided. • This data should be automatically populated via integration between clinical systems.		
Verification rules	Valid version of the **grading system** recorded.		

2.3.8 Recurrence type

The recurrence type provides additional detail to describe diagnosis and contextualise treatment.

Definition	The type of recurrence being treated.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain			
Obligation	Optional		
Guide for use	-		
Verification rules	Must be an active SNOMED CT concept.		

Clinical term	SCTID
Local	TBA
Regional	TBA
Locoregional	TBA
Distant	TBA
Unknown	TBA

2.3.9 Recurrence date

Definition	The date of recurrence.		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Optional		
Guide for use	-		
Verification rules	A valid date that is less than or equal to the current date.		

2.4 Observation

Information relating to overall patient assessment.

2.4.1 ECOG status date

Definition	The date when the patient's ECOG status was derived or agreed.		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Mandatory		
Guide for use	• This data should be automatically populated via integration between clinical systems.		
Verification rules	A valid date that is less than or equal to the current date.		

2.4.2 ECOG status

The ECOG status is critical to contextualise the treatment a person is receiving.

Definition	The ECOG status at the start of the regimen as defined by Eastern Cooperative Oncology Group (ECOG).		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)

Value domain	See '**ECOG status**' in **Appendix A: Additional SNOMED CT terms**
Obligation	Mandatory
Guide for use	• Useful for comparing ECOG thresholds for the same course of treatment. • More widespread than KPS (simpler and easier to use). • Important to tie treatments to outcomes. • This data should be automatically populated via integration between clinical systems.
Verification rules	Must be an active SNOMED CT concept.

2.5 Staging

This section lists the data elements for capturing the patient's staging information. Staging systems classify patients with a similar prognosis into groups or stages.

TNM staging is an international staging classification system based on the anatomical site of the primary tumour and the extent of its spread.

- The T (tumour) component refers to the size of the tumour and whether it has spread to surrounding tissues.
- The N (nodes) component describes the presence or absence of tumour in regional lymph nodes.
- The M (metastasis) component refers to the presence or absence of tumour at sites distant from the primary cancer type.

When clinically appropriate, at least one T, N or M needs to be recorded across the clinical and pathological settings (eg a Clinical or Pathological T must be provided, and so on). TNM Staging is only applicable when the diagnosis is for an adult (>16 years of age) non-haematological, non-CNS or non-skin cancer.

Where AJCC is not clinically appropriate, 'Other staging system' elements can be recorded.

The staging section in this standard differs slightly from the HISO 10038.4 Cancer Multidisciplinary Meeting Data Standard. This is to reflect the way that staging data is universally captured within the oncology electronic-prescribing systems from which the data will be sourced.

NOTE: Te Aho o Te Kahu (Cancer Control Agency), is undertaking projects to improve the quality and completeness of staging data. This section will be updated to reflect the outcome of this project. Please contact Te Aho o Te Kahu (Cancer Control Agency) for further information by emailing **info@teaho.govt.nz**.

2.5.1 Clinical stage

Clinical stage classification **(cTNM)** is based on patient history, physical examination, and any imaging done before initiation of treatment. Imaging study information may be used for clinical staging, but clinical stage may be assigned based on whatever information is available. No specific imaging is required to assign a clinical stage for any cancer site. When performed within this framework, biopsy information on regional lymph nodes and/or other sites of metastatic disease may be included in the clinical classification (source: AJCC 8th edition).

The following data elements identify the key information that helps to determine a suitable treatment option for a patient.

TNM: Clinical T stage

Definition	Clinical T stage is the coding system used to identify the presence of a primary tumour. It reflects the tumour size and extent of the primary cancer.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	SNOMED CT identifier that refers to the valid T category code.		
Obligation	Optional		
Guide for use	A system should allow the user to select an appropriate TNM category code using the correct SNOMED CT identifier.		
Verification rules	Must be an active SNOMED CT concept.		

TNM: Clinical N stage

Definition	Clinical N stage is the coding system used to denote the absence or presence of regional lymph node metastases. It classifies the extent of regional lymph node metastases.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	SNOMED CT identifier that refers to the valid N category code.		
Obligation	Optional		
Guide for use	A system should allow the user to select an appropriate TNM category code using the correct SNOMED CT identifier.		
Verification rules	Must be an active SNOMED CT concept.		

TNM: Clinical M stage

Definition	Clinical M stage is the coding system used to record the absence or presence of distant metastases.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	SNOMED CT identifier that refers to the valid M codes from the current edition of the AJCC TNM *Classification of Malignant Tumours*.		
Obligation	Optional		
Guide for use	A system should allow the user to select an appropriate TNM category code using the correct SNOMED CT identifier.		
Verification rules	Must be an active SNOMED CT concept.		

Clinical TNM edition used

Definition	Staging system edition number used.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	**Clinical term** / **SCTID** **American Joint Commission on Cancer, *Cancer Staging Manual*, 7th edition neoplasm staging system** / 443830009 **American Joint Commission on Cancer, *Cancer Staging Manual*, 8th edition neoplasm staging system** / 897275008		
Obligation	Conditional; mandatory if **2.5.1 TNM: Clinical T,N,M or group stage** is provided.		
Guide for use	• This data should be automatically populated via integration between clinical systems. • The nationally agreed standardised classification to use for staging is AJCC TNM *Classification of Malignant Tumours*, 8th edition, January 2017.		
Verification rules	Must be an active SNOMED CT concept.		

Clinical group stage

Definition	Clinical group stage is determined from aggregate information on the primary tumour (T), regional lymph nodes (N), and distant metastases (M), as well as any specific prognostic factors for certain cancer types.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	SNOMED CT identifier that refers to the valid group stage codes.		
Obligation	Optional		
Guide for use	• This data should be automatically populated via integration between clinical systems. • Ensure that the edition number of the classification is recorded. • Refer to the AJCC TNM *Classification of Malignant Tumours* for coding rules. • Collect this data element from information provided by the treating doctor and recorded on the patient's medical record. • Collection of this data element is conditional on the disease site being listed in the AJCC TNM *Classification of Malignant Tumours*.		
Verification rules	Must be an active SNOMED CT concept.		

Clinical stage date

Definition	Clinical stage date is the date of decision to treat.		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Conditional; mandatory if **2.5.1 TNM: Clinical T,N,M or group stage** is provided.		
Guide for use	• This data should be automatically populated via integration between clinical systems.		
Verification rules	A valid date that is less than or equal to the current date.		

2.5.2 Pathological stage

Pathological stage classification **(pTNM)** is based on clinical stage information supplemented/modified by operative findings and pathological evaluation of the resected specimens. This classification applies when surgery is performed before initiation of adjuvant radiation or systemic therapy (source: AJCC 8th edition).

The following data elements identify the key information that helps to determine a suitable treatment option for a patient.

TNM: Pathological T stage

Definition	Pathological T stage is the coding system used to identify the presence of primary tumour. It reflects the tumour size and extent of the primary cancer.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	SNOMED CT identifier that refers to the valid T category code.		
Obligation	Optional		
Guide for use	• This data should be automatically populated via integration between clinical systems. • A system should allow the user to select an appropriate TNM category code using the correct SNOMED CT identifier.		
Verification rules	Must be an active SNOMED CT concept.		

TNM: Pathological N stage

Definition	Pathological N stage is the coding system used to denote the absence or presence of regional lymph node metastases. It classifies the extent of regional lymph node metastases.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	SNOMED CT identifier that refers to the valid N category code.		
Obligation	Optional		
Guide for use	• This data should be automatically populated via integration between clinical systems. • A system should allow the user to select an appropriate TNM category code using the correct SNOMED CT identifier.		
Verification rules	Must be an active SNOMED CT concept.		

TNM: Pathological M stage

Definition	Pathological M stage is the coding system used to record the absence or presence of distant metastases.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	SNOMED CT identifier that refers to the valid M category code.		
Obligation	Optional		
Guide for use	• This data should be automatically populated via integration between clinical systems. • A system should allow the user to select an appropriate TNM category code using the correct SNOMED CT identifier.		
Verification rules	Must be an active SNOMED CT concept.		

Pathological TNM edition used

Definition	Staging system edition number used.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	**SCTID** / **Clinical term** 443830009 / **American Joint Commission on Cancer, *Cancer Staging Manual*, 7th edition neoplasm staging system** 897275008 / **American Joint Commission on Cancer, *Cancer Staging Manual*, 8th edition neoplasm staging system**		
Obligation	Conditional; mandatory if **2.5.2 TNM: Pathological T,N,M or group stage** is provided.		
Guide for use	• This data should be automatically populated via integration between clinical systems • The nationally agreed standardised classification to use for staging is AJCC TNM *Classification of Malignant Tumours*, 8th edition, January 2017		
Verification rules	Must be an active SNOMED CT concept.		

Pathological group stage

Definition	Pathological group stage is determined from aggregate information on the primary tumour (T), regional lymph nodes (N), and distant metastases (M), as well as any specific prognostic factors for certain cancer types.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	SNOMED CT identifier that refers to the valid group stage codes.		
Obligation	Optional		
Guide for use	• This data should be automatically populated via integration between clinical systems. • Record the edition number of the classification. • Refer to the AJCC TNM *Classification of Malignant Tumours* for coding rules. • Collect this data element from information provided by the treating doctor and recorded on the patient's medical record. • Collection of this data element is conditional on the disease site being listed in the AJCC TNM *Classification of Malignant Tumours*.		
Verification rules	Must be an active SNOMED CT concept.		

Pathological stage date

Definition	Pathological stage date is the date at time of the surgery (ie, the date the specimen was collected).		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Conditional; mandatory if **2.5.2 TNM: Pathological T,N,M or group stage** is provided.		
Guide for use	This data should be automatically populated via integration between clinical systems.		
Verification rules	A valid date that is less than or equal to the current date.		

2.5.3 Other staging

Where TNM is not used or is not applicable, details of another staging system can be recorded using the following data elements.

The following data elements identify the key information that helps to determine a suitable treatment option for a patient.

Other staging system group stage

Definition	This describes the anatomical extent of disease at diagnosis based on stage categories of a staging classification other than the standard TNM classification.		
Source standards	-		
Data type	Alphanumeric	**Representational class**	Free text
Field size	10	**Representational layout**	N(10)
Value domain	Supplementary values: **Term** / **Code** Not applicable / 8888888888 Unknown / 9999999999		
Obligation	Optional		
Guide for use	• Applies to all cancer stage groupings where a staging classification other than the standard TNM classification is used. A separate data element captures TNM stage grouping. • Record valid stage grouping codes from the current edition of the appropriate staging source for the cancer.		
Verification rules			

Other staging system

Definition	Staging classification system other than TNM.		
Source standards	-		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)

Value domain	**Clinical term** / **SCTID** FIGO staging system of gynaecological malignancy — 254383006 Chronic Lymphocytic Leukaemia CLL International Prognostic Index (CLL-IPI) — 1149100002 Binet Staging Classification for Chronic Lymphocytic Leukaemia — 1149099005 Breslow system for melanoma staging — 385346008 Rai staging system for Chronic Lymphocytic Leukaemia — 1149131009 Ann Arbor lymphoma staging system — 254372002 International Staging System (ISS) for myeloma — 1149162008 Revised International Staging System (R-ISS) for myeloma — 1149163003 Australian Clinico-pathological Staging (ACPS) system for colorectal cancer — 1149164009 Other — 74964007 Unknown — 261665006 Note: This list will be revised in a future review.
Obligation	Conditional; mandatory if **2.5.3 Other staging system group stage** is provided.
Guide for use	• This data should be automatically populated via integration between clinical systems. • TNM staging is not applicable to all tumour sites. Staging is of limited use in some cancers, for example, haematological malignancies. In these cases, use the most appropriate classification system. • Use the current edition of each staging scheme.
Verification rules	Must be an active SNOMED CT concept.

Other staging system version

Definition	Version number of staging classification system other than TNM.		
Source standards	-		
Data type	Alphanumeric	**Representational class**	Free text
Field size	10	**Representational layout**	N(10)
Value domain	Number, 1–87 **Term** / **Code** Not applicable — 88 Unknown edition — 99		
Obligation	Conditional; mandatory if **2.5.3 Other staging system group stage** is provided.		
Guide for use	Record the version number of the staging system used to stage this diagnosis of cancer.		

Verification rules	A valid version of the **Other staging system** recorded.

Other staging system stage date

Definition	The date when the patient's overall cancer stage was derived or agreed.		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Conditional; mandatory if **2.5.3 Other staging system group stage** is provided.		
Guide for use	-		
Verification rules	A valid date that is less than or equal to the current date.		

2.6 Prognostic scoring

Information relating to prognostic scoring.

Prognostic scoring is critical in describing the cancer diagnosis for most haematological cancers and some solid tumours.

2.6.1 Prognostic score

Definition	The prognostic score on which the cancer treatment is being prescribed.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain			

Clinical term	SCTID
TBA	TBA
TBA	TBA
TBA	TBA
TBA	TBA
TBA	TBA

Obligation	Optional
Guide for use	- TBA
Verification rules	Must be an active SNOMED CT concept.

2.6.2 Prognostic score date

Definition	The date when the patient's prognostic score was derived or agreed.		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Conditional; mandatory if **2.6.2 Prognostic score** is provided.		
Guide for use	This data should be automatically populated via integration between clinical systems.		
Verification rules	A valid date that is less than or equal to the current date.		

2.6.3 Prognostic scoring edition

Definition	The edition of the prognostic scoring system.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain			

Clinical term	SCTID
TBA	TBA
TBA	TBA
TBA	TBA
TBA	TBA
TBA	TBA

Obligation	Conditional; mandatory if **2.6.2 Prognostic score** is provided.
Guide for use	• This data should be automatically populated via integration between clinical systems.
Verification rules	Must be an active SNOMED CT concept.

2.6.4 Prognostic scoring system

Definition	The prognostic scoring system used.		
Source standards	-		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)

Value domain	<table><tr><th>Clinical term</th><th>SCTID</th></tr><tr><td>Nottingham prognostic index</td><td>414879002</td></tr><tr><td>IPI- International Prognostic Index</td><td>716567001</td></tr><tr><td>Follicular Lymphoma International Prognostic Index</td><td>708736003</td></tr><tr><td>MIPI - Mantle Cell Lymphoma International Prognostic Index</td><td>763236005</td></tr><tr><td>CLL-IPI - Chronic Lymphocytic Leukemia International Prognostic Index</td><td>1149100002</td></tr><tr><td>TBA</td><td>TBA</td></tr></table>
Obligation	Conditional; mandatory if **2.6.2 Prognostic score** is provided.
Guide for use	• This data should be automatically populated via integration between clinical systems.
Verification rules	Must be an active SNOMED CT concept.

2.7 Regimen

Information relating to a patient's treatment plan.

2.7.1 SRL regimen code

This data element is critical for linking the regimen a patient is receiving back to the **SACT Regimen Library (SRL)**.

Definition	The SACT Regimen Library ID of the regimen a person is receiving.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	**SACT Regimen Library (SRL)**		
Obligation	Conditional; mandatory if a **SRL regimen** is provided.		
Guide for use	• This data should be automatically populated via integration between clinical systems.		
Verification rules	Must be an active SNOMED CT concept.		

2.7.2 Regimen ID

This data element details the identifier of the regimen used in the treatment where an SRL regimen is not available/provided, and a local unique identifier is used.

Definition	Local unique ID of the regimen.		
Purpose	Records the regimen used in the treatment.		
Source standards	-		
Data type	Alphanumeric	**Representational class**	Identifier
Field size	TBA	**Representational layout**	X(TBA)
Value domain	As defined by the local system		
Obligation	Mandatory		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems.		
Verification rules			

2.7.3 Regimen name

The regimen name is critical for describing the treatment a patient is receiving.

Definition	The name of the regimen/careplan.		
Source standards			
Data type	Alphanumeric	**Representational class**	Free text
Field size	TBA	**Representational layout**	X(TBA)
Value domain	Valid name assigned from the **SACT Regimen Library** or the name defined by the local system.		
Obligation	Mandatory		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • If a SACT Regimen Library (SRL) regimen is used, then this field should reflect the exact SRL regimen name. **https://nzf.org.nz/regimens?preview=true**		
Verification rules	For SRL regimens, must be the name assigned to the SRL regimen ID.		

2.7.4 Treatment intent

The treatment intent characterises the expectation of whether treatment is either curative or palliative.

Definition	The intent of the treatment regimen.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	**Clinical term** / **SCTID** **Adjuvant** 373846009 **Neo-adjuvant** 373847000 **Curative** 373808002 **Palliative** 363676003 **Supportive** 399707004		
Obligation	Mandatory, optional for haematology primary cancer types.		
Guide for use	-		
Verification rules	Must be an active SNOMED CT concept.		

2.7.5 Clinical trial flag

The clinical trial flag will provide valuable information on understanding access to clinical trials.

Definition	Indicates whether the regimen is a clinical trial		
Source standards	-		
Data type	Boolean	**Representational class**	N/A
Field size	1	**Representational layout**	N(1,0)
Value domain	1 **Yes.** The regimen is a clinical trial 0 **No.** The regimen is not a clinical trial		
Obligation	Optional		
Guide for use	• This data should be automatically populated via integration between clinical systems. • It is acknowledged that not all clinical trial data is captured within existing electronic systems.		
Verification rules	Valid value only		

2.7.6 Regimen complete flag

Definition	Indicates whether the full regimen has been completed by the patient.		
Source standards	-		
Data type	Boolean	**Representational class**	N/A
Field size	1	**Representational layout**	N(1,0)
Obligation	1 **Yes.** The full regimen was completed by the patient 0 **No.** The full regimen was not completed by the patient		
Guide for use	Mandatory		
Verification rules	• This data should be automatically populated		
	Valid value only		

2.7.7 Discontinue date

Capturing the date the regimen was discontinued is important to understand variation in treatment discontinuation rates.

Definition	Date the regimen was discontinued		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Conditional; mandatory if regimen has been completed or discontinued		
Guide for use	-		
Verification rules	A valid date that is less than or equal to the current date.		

2.7.8 Discontinue reason

Information relating to reasons for treatment discontinuation.

This information is important to understand variation in treatment discontinuation rates and reasons.

Overall discontinue reason

Definition	The reason the regimen was discontinued		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)

Value domain	See '**Overall discontinue reason'** in **Appendix A: Additional SNOMED CT terms**
Obligation	Conditional; mandatory if **2.7.4 Discontinue date** is provided.
Guide for use	-
Verification rules	Must be an active SNOMED CT concept.

Discontinue reason due to patient factors

A key objective of ACT-NOW is to identify barriers to access and reasons for treatment discontinuation. Patient factors can play a key role in this and capturing data on patient factors has been identified as an ideal.

Definition	The patient factors resulting in treatment discontinuation.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	See '**Overall discontinue reason due to patient factors'** in **Appendix A: Additional SNOMED CT terms**		
Obligation	Optional		
Guide for use	• Tier 2 of a discontinue reason selection. • Multiple options can be selected.		
Verification rules	Must be an active SNOMED CT concept.		

Discontinue reason due to toxicity type

A key objective of ACT-NOW is to identify reasons for treatment discontinuation. Toxicities can play a key role in this and capturing toxicity data has been identified as an ideal.

Definition	Toxicities resulting in treatment discontinuation.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	See '**Overall discontinue reason due to toxicity type'** in **Appendix A: Additional SNOMED CT terms**		
Obligation	Optional		
Guide for use	• Tier 2 of a discontinue reason selection. • Multiple options can be selected.		
Verification rules	Must be an active SNOMED CT concept.		

2.7.9 Number of cycles administered

Collecting details about the number of cycles administered in a regiment is important to understand variation in practice.

Definition	The number of cycles administered in a regimen.		
Source standards	-		
Data type	Numeric	**Representational class**	Value
Field size	3	**Representational layout**	N(3)
Value domain	An integer		
Obligation	Required		
Guide for use	• This data should be automatically populated via integration between clinical systems.		
Verification rules	A valid value		

2.7.10 Disease response

Capturing information on the disease response will provide meaningful yet simple outcomes data for curative treatments.

Definition	Disease response category for curative treatments.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain			
Obligation	Conditional; mandatory if **2.7.1 Treatment intent** value **'Curative'** is provided.		
Guide for use	-		
Verification rules	Must be an active SNOMED CT concept.		

Clinical term	SCTID
Complete response	TBA
Not complete response	TBA
No response	TBA
Partial response	TBA
TBA	TBA

2.7.11 Date of completion

Definition	The date the planned treatment regimen was completed.		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Conditional, Mandatory if the regimen has been completed		
Guide for use	• This data should be automatically populated via integration between clinical systems.		
Verification rules	A valid date that is less than or equal to the current date.		

2.8 Cycle

Information relating to a cycle, the period of chemotherapy treatment given according to a specific schedule.

The cycle number, length, start date, end date and last administration date are used as mechanisms to link the regimen details to the administration details.

2.8.1 Cycle number

Definition	The sequential cycle number within the regimen		
Source standards	-		
Data type	Numeric	**Representational class**	Value
Field size	3	**Representational layout**	N(3)
Value domain	An integer		
Obligation	Mandatory		
Guide for use	• This data should be automatically populated via integration between clinical systems. • This data should be automatically populated via integration between clinical systems.		
Verification rules	A valid value greater than zero		

2.8.2 Cycle length

Definition	The intended length of the cycle in a regimen.		
Source standards	-		
Data type	Numeric	**Representational class**	Value

Field size	3	**Representational layout**	N(3)
Value domain	An integer		
Obligation	Mandatory		
Guide for use	• This data should be automatically populated via integration between clinical systems. • This data should be automatically populated via integration between clinical systems.		
Verification rules	A valid value		

2.8.3 Cycle start date

Definition	The date the cycle of treatment starts.		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Mandatory		
Guide for use	• This data should be automatically populated via integration between clinical systems. • This data should be automatically populated via integration between clinical systems.		
Verification rules	A valid date that is less than or equal to the current date.		

2.8.4 Cycle end date

Definition	The date the cycle of treatment ends.		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Mandatory		
Guide for use	• This data should be automatically populated via integration between clinical systems. • This data should be automatically populated via integration between clinical systems.		
Verification rules	A valid date that is greater than or equal to the **Cycle start date** and less than or equal to the current date.		

2.8.5 Last administration date

Definition	The date of the last administration during the corresponding cycle (for orals this is the last prescription date).		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Mandatory		
Guide for use	• This data should be automatically populated via integration between clinical systems.		
Verification rules	A valid date that is less than or equal to the current date.		

2.8.6 Dose adjustment reason

Capturing the reason for adjustments is necessary to understand variation in dosing/dose adjustments.

Definition	Reason for dose adjustments that apply to a cycle.		
Source standards	-		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	See '**Dose adjustment reason**' in **Appendix A: Additional SNOMED CT terms**		
Obligation	Conditional; mandatory if all **2.9.4 Prescribed dose** values and **2.9.2 Administered dose values** for a **2.9.3 Medicine ID** in the cycle differ by the same amount		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems if dose adjustments are made at the regimen or cycle level.		
Verification rules	Must be an active SNOMED CT concept.		

2.8.7 Body Surface Area (BSA)

Knowing the body surface area of a patient at the start of the cycle will provide valuable information to understand variation in dose-capping.

Definition	The BSA at the start of the cycle in metres squared.		
Source standards	-		
Data type	Numeric	**Representational class**	Value

Field size	3	**Representational layout**	N.NN
Value domain	Metres squared (m^2)		
Obligation	Mandatory depending on regimen		
Guide for use	*Note: TBA if BSA should be recorded to at least one decimal place.* • Neither the word 'metres squared' nor the abbreviation 'm^2' should be included in the value of this data element.		
Verification rules	Value greater than zero.		

2.8.8 Weight

Capturing the weight of a patient at the time of encounter is a Health and Disability Commissioner (HDC) requirement.

Definition	The measured weight of the patient at the time of the encounter.		
Source standards	-		
Data type	Numeric	**Representational class**	Value
Field size	5	**Representational layout**	NNN.N
Value domain	Kilograms		
Obligation	Optional		
Guide for use	• Record weight to one decimal place. • Neither the word 'kilograms' nor the abbreviation 'kg' should be included in the value of this data element.		
Verification rules	Value greater than zero.		

2.8.9 Creatinine clearance

For some regimens, creatinine clearance is critical to inform/contextualise dosing.

Definition	Creatinine clearance used to prescribe the drug		
Source standards	-		
Data type	Numeric	**Representational class**	Value
Field size	5	**Representational layout**	N(5)
Value domain	An integer		
Obligation	Optional		
Guide for use	• TBA, unit of measure		
Verification rules	Value greater than zero.		

2.8.10 Creatinine clearance date

The date the creatinine clearance sample was obtained.

Definition	Date on which the creatinine clearance was measured		
Source standards	-		
Data type	Date	**Representational class**	Full date
Field size	8	**Representational layout**	YYYYMMDD
Value domain	Valid date		
Obligation	Conditional; mandatory if **2.8.8 Creatinine clearance** is provided.		
Guide for use	-		
Verification rules	A valid date that is less than or equal to the current date.		

2.9 Administration

Information relating to treatment administration to a patient.

The data elements identified in this section are key to providing an understanding of the treatment information.

2.9.1 Cycle day

Definition	The day in a cycle a dose is administered.		
Source standards	-		
Data type	Numeric	**Representational class**	Value
Field size	3	**Representational layout**	N(3)
Value domain	An integer		
Obligation	Mandatory		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems.		
Verification rules	Value greater than zero.		

2.9.2 Medicine name

Definition	The name of the medicine being administered.		
Source standards	NZ Medicines Terminology		
Data type	Alphanumeric	**Representational class**	Free text
Field size	TBA	**Representational layout**	X(TBA)
Value domain	Must be a valid NZ Medicines Terminology medicine		
Obligation	Mandatory		

Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems. • Captured when a drug is administered.
Verification rules	Must be the name assigned to the **Medicine ID**.

2.9.3 Medicine ID

Definition	The unique ID of the medicine administered.		
Source standards	HISO 10024.1:2018 New Zealand Universal List of Medicines		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	NZMT TPUU SCTID		
Obligation	Mandatory		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems. • Captured when a drug is administered. This data element records the **New Zealand Medicines Terminology** (NZMT) identifier for the specific Trace Product Unit of Use (TPUU) TPUU identifies a specific vaccine, its does form and strength – for example an injectable unit does of a given product. TPUU code can be used to lookup the trade product name in the **NZ Universal List of Medicines** (NZULM) and the associated non-proprietary Medicinal Product Unit of Use (MPUU) details, which include does form and strength. MPUU, in turn, is linked to non-proprietary Medical Product (MP) entities in the NZMT and from there to the SNOMED CT The codes used to identify the different NZMT entity types are all SNOMED CT identifiers (SCTIDs).		
Verification rules	Must be identifier assigned to the **Medicine name**.		

2.9.4 Prescribed dose

Definition	The dose according to the selected regimen/cycle.		
Source standards	-		
Data type	Numeric	**Representational class**	Value

Field size	3	**Representational layout**	N(3)
Value domain	An integer		
Obligation	Mandatory		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems.		
Verification rules	Valid value greater than zero.		

2.9.5 Prescribed dose unit

Definition	The dose unit according to the selected regimen/cycle prescribed.		
Source standards	HISO 10080:2021 Systemic Anti-Cancer Therapy Regimen Data Standard		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	Valid code from '**Dose unit**' in **5.2.6 HISO 10080:2021 Systemic Anti-Cancer Therapy Regimen Data Standard**		
Obligation	Mandatory		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems.		
Validation rules	Must be an active SNOMED CT concept.		

2.9.6 Administered dose

Definition	The administered dose.		
Source standards	-		
Data type	Numeric	**Representational class**	Value
Field size	3	**Representational layout**	N(3)
Value domain	An integer		
Obligation	Mandatory		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems.		
Verification rules	Value greater than zero.		

2.9.7 Administered dose unit

Definition	The unit of measure used for a single dose when the medication was administered to a patient.		
Source standards	HISO 10080:2021 Systemic Anti-Cancer Therapy Regimen Data Standard		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	Valid code from '**Dose unit**' in **5.2.6 HISO 10080:2021 Systemic Anti-Cancer Therapy Regimen Data Standard**		
Obligation	Mandatory		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy • This data should be automatically populated via integration between clinical systems.		
Validation rules	Must be an active SNOMED CT concept.		

2.9.8 Route of administration

Definition	The value set the route by which the regimen specifies a medicine is administered to the patient.		
Source standards	HISO 10080:2021 Systemic Anti-Cancer Therapy Regimen Data Standard		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	Valid code from '**Route of administration**' in **5.2.8 HISO 10080:2021 Systemic Anti-Cancer Therapy Regimen Data Standard**		
Obligation	Mandatory		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems.		
Validation rules	Must be an active SNOMED CT concept.		

2.9.9 Administration start time

Definition	Date and time of administration start		
Source standards	-		
Data type	Date/time	**Representational class**	Full date and time
Field size	14	**Representational layout**	YYYYMMDD HH:MM
Value domain	Valid date and time		
Obligation	Conditional; mandatory if **2.9.1 Route of administration** value **'oral administration'** is not provided.		

Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems.
Verification rules	This must be a valid date and time that is less than or equal to the current date and time.

2.9.10 Administration end time

Definition	Datetime of administration end		
Source standards	-		
Data type	Date/time	**Representational class**	Full date and time
Field size	14	**Representational layout**	YYYYMMDD HH:MM
Value domain	Valid date and time		
Obligation	Conditional; mandatory if **2.9.1 Route of administration** value **'oral administration'** is not provided.		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems.		
Verification rules	This must be a valid date and time that is greater than or equal to the current date and time.		

2.9.11 Administration duration

Definition	Administration duration in minutes		
Source standards	-		
Data type	Numeric	**Representational class**	Value
Field size	3	**Representational layout**	N(3)
Value domain	An integer		
Obligation	Conditional; mandatory if **2.9.1 Route of administration** value **'oral administration'** is not provided.		
Guide for use	• It is recommended that this data element be captured to allow for prescribing of systemic anti-cancer therapy. • This data should be automatically populated via integration between clinical systems.		
Verification rules	Value greater than zero.		

2.10 Tumour specific elements

This lists the details required for specific tumours.

Note: These elements are subject to change following completion of related data specifications in Te Aho o Te Kahu's Structured Pathology project. Data elements that are needed for publicly available treatments should be mandatory. Prognostic scores should be optional.

2.10.1 Breast

Estrogen Receptor (ER) status

Definition	The Estrogen Receptor (ER) status obtained from a patient with breast cancer		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	**Clinical term** / **SCTID** Estrogen receptor negative neoplasm / 441117001 Estrogen receptor positive tumor / 416053008		
Obligation	Optional		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

Progesterone Receptive (PR) status

Definition	A code that specifies whether the tumour is progesterone receptive (PR) or not.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

HER2 status

Definition	A code for the human epidermal growth factor receptor 2 status of the tumour.		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

2.10.2 Lung

EGFR

Definition	Epidermal Growth Factor Receptor status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

ALK

Definition	Anaplastic lymphoma kinase (ALK) status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

2.10.3 Bowel

MSI

Definition	Microsatellite instability status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

BRAF

Definition	BRAF mutation status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

2.10.4 Head and Neck

HPV16

Definition	Human papillomavirus 16 status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

2.10.5 CNS – GBM

IDH

Definition	Isocitrate dehydrogenase status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

Methylation status (variant)

Definition	Methylation status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

2.10.6 Generic

PD1

Definition	PD1 protein status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

PD1L

Definition	Programmed death-ligand 1 status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

2.10.7 Testes

LDH

Definition	Lactate dehydrogenase status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

AFP

Definition	Alpha-fetoprotein status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

HCG

Definition	Human chorionic gonadotropin status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)

Value domain	TBA
Obligation	TBA
Guide for use	
Verification rules	Must be an active SNOMED CT concept.

IGCCCG

Definition	The International Germ Cell Cancer Collaborative Group status		
Source standards	**SNOMED CT New Zealand Edition**		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

2.10.8 Renal

To be determined

Definition			
Source standards	SNOMED CT New Zealand Edition		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

2.10.9 Haem

To be determined

Definition			
Source standards	SNOMED CT New Zealand Edition		
Data type	Numeric	**Representational class**	Code
Field size	18	**Representational layout**	N(18)
Value domain	TBA		
Obligation	TBA		
Guide for use			
Verification rules	Must be an active SNOMED CT concept.		

3 ADOPTION AND IMPLEMENTATION

3.1 Adoption roadmap

Te Aho o Te Kahu will lead national adoption of this standard as an element of the ACT-NOW project under the Cancer Action Plan 2019-2029.

The adoption roadmap includes:

- publication of approved national standard regimens to **https://nzf.org.nz/regimens**.
- uptake of published regimens by individual cancer units for new patients via manual inclusion into patient care plans created in cancer management software. This supports the capture of data about patient management across the country required by the Cancer Action Plan.
- addition of new functionality allowing for the electronic import and export of systemic therapy data to and from cancer management systems via FHIR API.
- Development of a national collection and analytics infrastructure to receive systemic therapy data via FHIR API.

3.2 Implementation principles

Key principles for the implementation of this standard include:

- must support capturing and sharing of information electronically while ensuring it is secure and protects patients' privacy according to the **Privacy Act 2020**, **Health Information Privacy Code 2020**, and the **HISO 10029:2015 Health Information Security Framework.**
- must be adaptable to apply new and modified data element requirements when future updates are published.
- should support integration with NHI, HPI, New Zealand Business Number (NZBN) and other master data sources referenced in this document.
- should integrate with other health information systems.
- should use automatically populated information if possible.
- should be used to support any Request for Proposal (RFP) process to select a SACT e-prescribing solution and/or as input into the design and development of this solution.
- should display the SNOMED preferred or clinically agreed term and capture the SNOMED concept identifier accordingly.
- SNOMED CT New Zealand Edition releases are currently published in April and October every year. All client systems should implement each release within three months of the release date. This implementation requirement may be revised in the future if the frequency of releases changes.

- Client system implementations of SNOMED CT New Zealand Edition should have the capability of processing data from previous versions of SNOMED CT.

APPENDIX A: ADDITONAL SNOMED CT TERMS

These are the SNOMED CT data domains (range of allowable options for a particular data element) for selected items in this standard. Both the SNOMED CT clinical term and identifier are presented. Any system should capture and submit to a national collection the clinical term, the associated code and the SNOMED CT version, but only the clinical term should be visible to users.

If a SNOMED CT code has not been provided, a suitable code either does not currently exist or code choices for the domain option are still under development. These will be added later. In this document, these entries are shown as TBA (to be advised). Reference sets for the below tables will be developed and included in a future release of the SNOMED CT New Zealand edition.

ECOG status

Clinical term	SCTID
ECOG performance status – grade 0 (Fully active, able to carry on all pre-disease performance without restriction)	425389002
ECOG performance status – grade 1 Restricted in physically strenuous activity but ambulatory and can carry out work of a light or sedentary nature (for example, light housework, office work)	422512005
ECOG performance status – grade 2 (Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50 percent of waking hours)	422894000
ECOG performance status – grade 3 (Capable of only limited self-care, confined to bed or chair more than 50 percent of waking hours))	423053003
ECOG performance status – grade 4 (Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair)	423237006
ECOG performance status – grade 5 (Dead)	423409001

Overall discontinue reason

Clinical term	SCTID
Toxicity	TBA
Disease progression	TBA
Patient factors	TBA
Treatment complete	TBA
Care plan change	TBA
Change of provider	TBA
Comorbidity (includes infection)	TBA
Deceased	TBA
Covid 19	TBA
Unable to contact patient	TBA

Discontinue reason due to patient factors

Clinical term	SCTID
Cost of drug	TBA
Travel barriers to accessing care	TBA
Other financial reason	TBA
Patient pursuing other treatment	TBA
Lack of psychosocial support	TBA
Lack of clinical support	TBA
Insufficient perceived benefit of treatment by patient	TBA
Not clarified with patient	TBA

Discontinue reason due to toxicity type

Clinical term	SCTID
Fatigue (drop in PS)	TBA
Diarrhoea	TBA
Nausea / vomiting	TBA
Neuropathy	TBA
Stomatitis (=oral mucositis)	TBA
Skin (rash, hand foot)	TBA
Allergy	TBA
Infection	TBA
Pulmonary	TBA
Cardiac	TBA
Vascular	TBA
Liver function	TBA
Renal function	TBA
Hearing	TBA

Dose adjustment reason

Clinical term	SCTID
Rounding	TBA
Age/Frailty	TBA
Weight change	TBA
Dose-capped	TBA
Adjusted Bodyweight	TBA
Performance status	TBA
Diarrhoea	TBA
Nausea / vomiting	TBA
Neuropathy	TBA
Fatigue	TBA
Stomatitis	TBA
Skin (rash, hand foot)	TBA
Allergy	TBA
Neutropenia	TBA
Thrombocytopenia	TBA
Liver function	TBA
Renal function	TBA
Lung toxicity	TBA
Hearing	TBA
Anaemia	TBA
Constipation	TBA
metabolic/mineral abnormality	TBA
Infection	TBA
Cardiac Toxicity	TBA
Other Toxicity	TBA