

From **ATC** to **ACG**: Implementing the Concomitant Medication Grouping (ACG) Dataset in Clinical Trial Analysis

Michelle Starkell

January 30th, 2026

The Role of ACG in Concomitant Medication Grouping

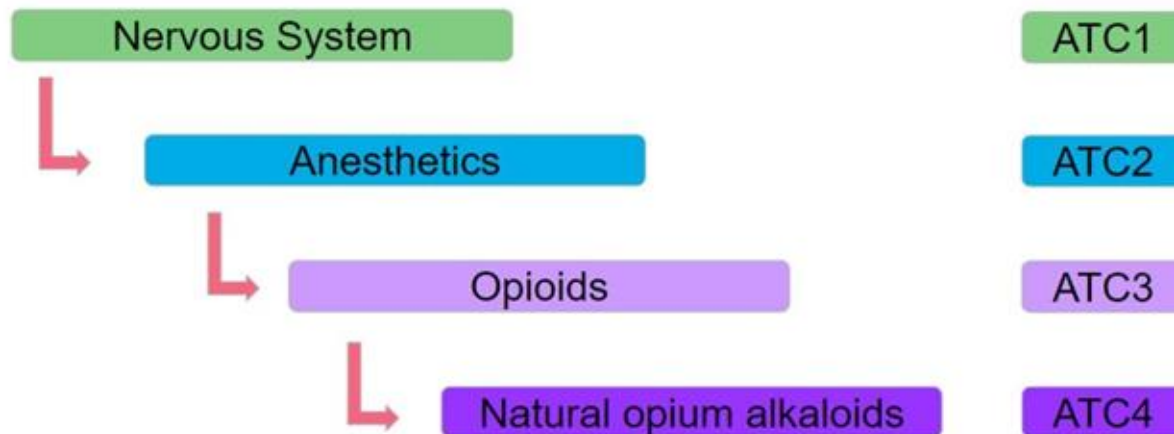
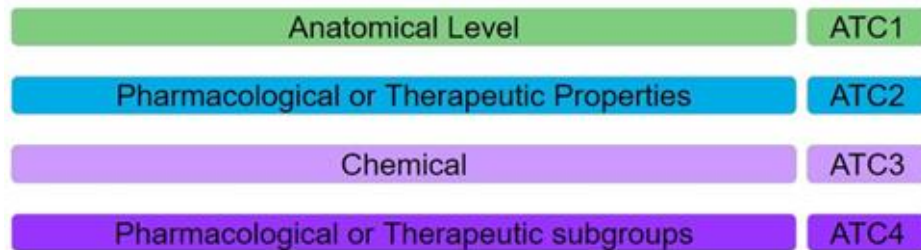
What is ACG?

- Concomitant Medication Grouping Definitions Dataset (ACG)
- Metadata dataset
- Categorizes concomitant medications into clinically meaningful drug groups at predefined classification levels

How does ACG support data analysis?

1. Supports the derivation of grouped summaries of concomitant medication use
2. Standardizes the application of WHO Drug Dictionary classifications via Anatomical Therapeutic Chemical (ATC) codes
3. Enables consistent downstream analyses

Understanding WHODrug ATC Levels



ATC Classification in Practice

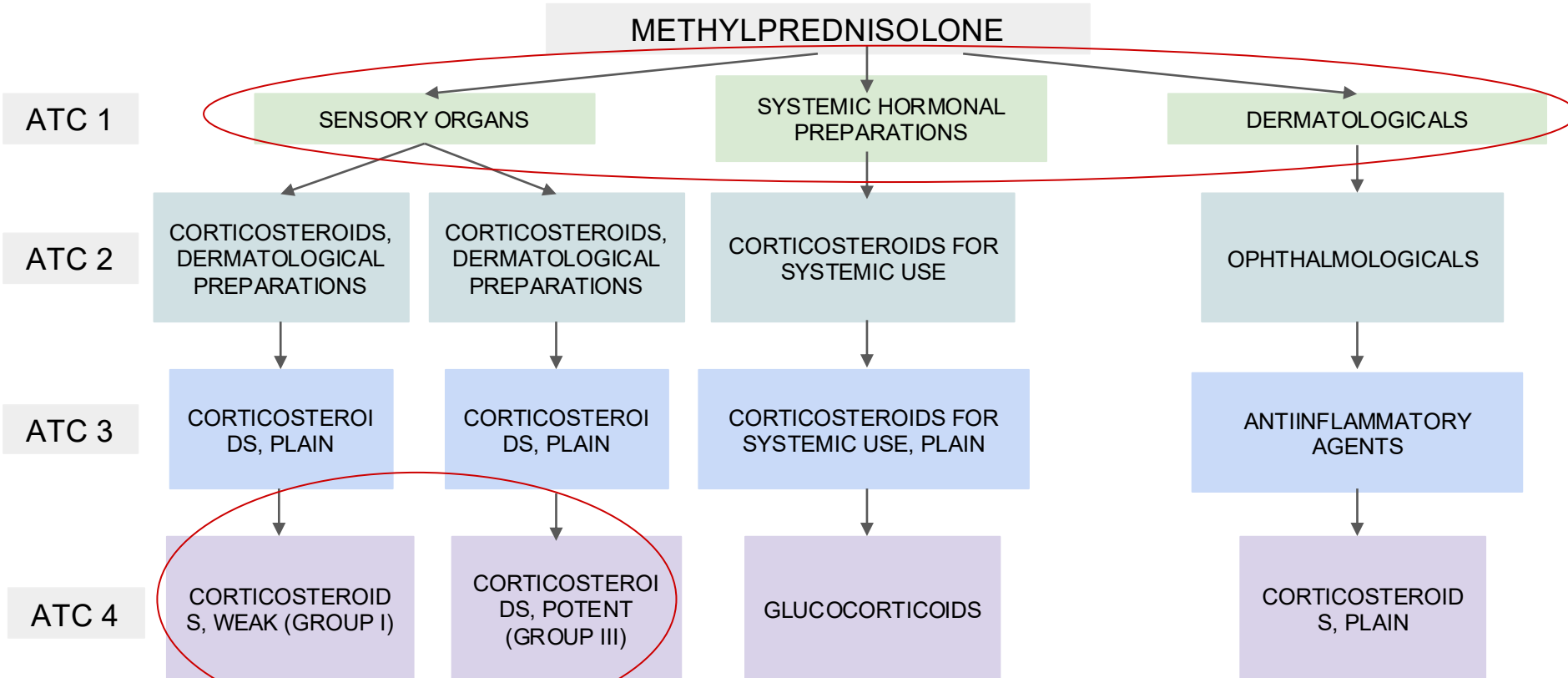
Multiple ATC Classification Paths for Methylprednisolone

CMTRT	CMSTDTC	CMDECOD	CMCAT
METHYLPREDNISOLONE	2024-10-02	METHYLPREDNISOLONE	CONCOMITANT



CMDECOD	ATC1	ATC1CD	ATC2	ATC2CD	ATC3	ATC3CD	ATC4	ATC4CD
METHYLPREDNISOLONE	DERMATOLOGICALS	D	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	D07	CORTICOSTEROIDS, PLAIN	D07A	CORTICOSTEROIDS, WEAK (GROUP I)	D07AA
METHYLPREDNISOLONE	DERMATOLOGICALS	D	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	D07	CORTICOSTEROIDS, PLAIN	D07A	CORTICOSTEROIDS, POTENT (GROUP III)	D07AC
METHYLPREDNISOLONE	SYSTEMIC HORMONAL PREPARATIONS	H	CORTICOSTEROIDS FOR SYSTEMIC USE	H02	CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN	H02A	GLUCOCORTICOIDS	H02AB
METHYLPREDNISOLONE	SENSORY ORGANS	S	OPHTHALMOLOGICALS	S01	ANTIINFLAMMATORY AGENTS	S01B	CORTICOSTEROIDS, PLAIN	S01BA

ATC Classification in Practice



Standard vs Custom Drug Groupings

SDGs

- WHO Drug Dictionary pre-defined baskets
- Common therapeutic groupings
- Readily implementable
- Use standard programming approaches
- *E.g. Corticosteroids for obstructive airway diseases*

Custom drug groupings

- Organization-specific or study-specific
- Addresses analytical needs not covered by SDGs
 - Specific drug groupings, disease-specific medication groups, safety-related groupings, etc
- *E.g. Nephrotoxic medications*

ACG defines, versions, and applies SDGs and CDGs across analysis datasets

The diagram illustrates the relationship between Standard Drug Groupings (SDGs) and Custom Drug Groupings (CDGs) in the context of the Analysis Classification Grouping (ACG). Two boxes at the top, 'SDGs' and 'Custom drug groupings', each have a large green arrow pointing down towards a central box labeled 'ACG'. The 'SDGs' box lists WHO pre-defined baskets, common therapeutic groupings, and standard programming approaches, with an example of corticosteroids for obstructive airway diseases. The 'Custom drug groupings' box lists organization-specific or study-specific groupings, addresses analytical needs not covered by SDGs (such as specific drug groupings, disease-specific medication groups, and safety-related groupings), and provides an example of nephrotoxic medications. The central 'ACG' box states that it defines, versions, and applies both SDGs and CDGs across analysis datasets.

Context

Using SDGs and CDGs in combination

- SDGs are useful for capturing medications relevant to broad indications
- Full range of medications relevant to disease area not covered by SDGs
 - Newly-approved agents
 - Drugs for specialized indications
 - List of prohibited medications

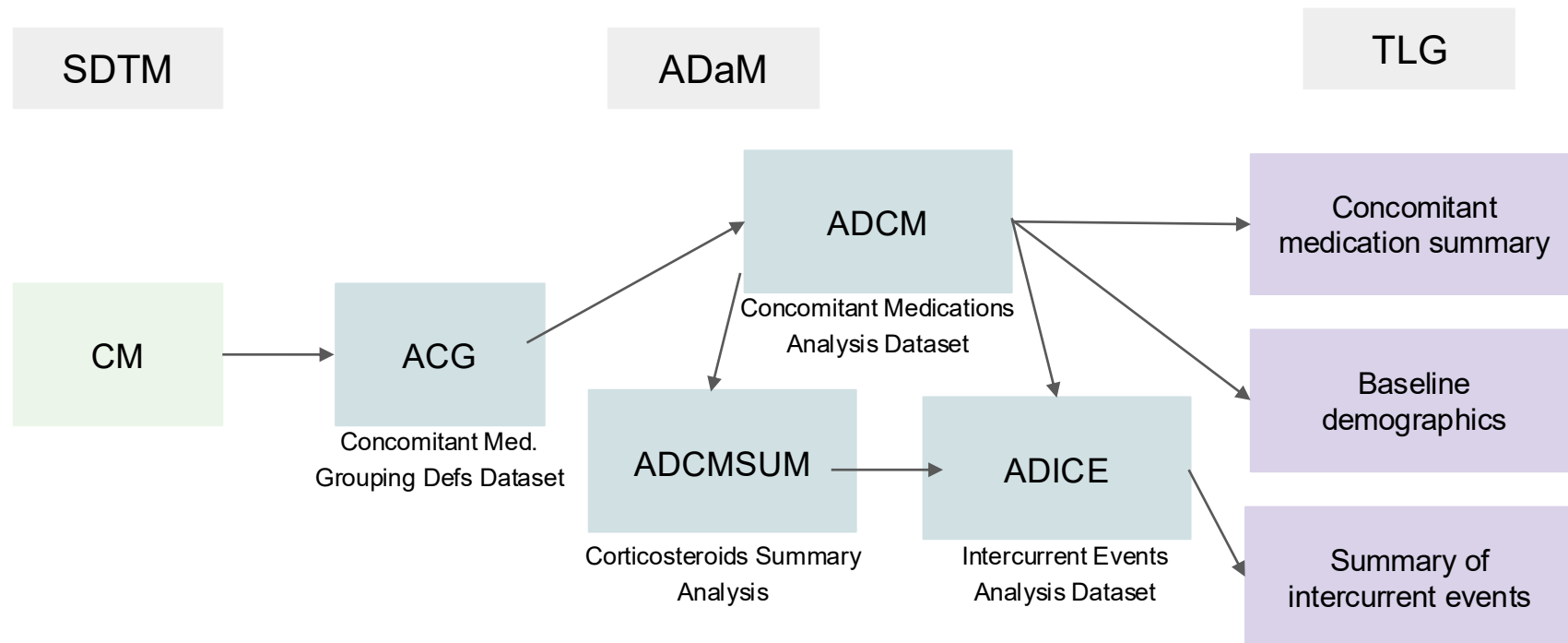
Reliance on solely SDGs is insufficient to identify thorough list of medications



Solution: Create a project-specific ACG to enable transparent documentation of drug grouping logic

Data Flow

ACG serves as the linkage between SDTM records and analysis-ready drug group ADaM flags



SDTM (CM) to ADaM (ACG)

One drug can be included in multiple drug groupings

CM

USUBJID	CMDECOD	CMPNCD
XXX-1001	METHYLPREDNISOLONE	00049601001
XXX-1002	DIPHENHYDRAMINE HYDROCHLORIDE	00000402001

ACG

PREFIX	TERMNAME	TERMID	GRPTYPE	GRPNAME	VERSION
SDG01	METHYLPREDNISOLONE	00049601001	SDG	Corticosteroids	WHODRUG GLOBAL B3 MARCH 1, 2025
SDG02	METHYLPREDNISOLONE	00049601001	SDG	Immunosuppressant drugs	WHODRUG GLOBAL B3 MARCH 1, 2025
SDG02	DIPHENHYDRAMINE HYDROCHLORIDE	00000402001	SDG	Immunosuppressant drugs	WHODRUG GLOBAL B3 MARCH 1, 2025

Implementation of ACG in ADCM

Depending on ACG, drugs may be flagged in **one**, **multiple**, or **no** groupings

ACG

PREFIX	TERMNAME	TERMID	GRPTYPE	GRPNAME	VERSION
SDG01	METHYLPREDNISOLONE	00049601001	SDG	Corticosteroids	WHODRUG GLOBAL B3 MARCH 1, 2025
SDG02	METHYLPREDNISOLONE	00049601001	SDG	Immunosuppressant drugs	WHODRUG GLOBAL B3 MARCH 1, 2025
SDG02	DIPHENHYDRAMINE HYDROCHLORIDE	00000402001	SDG	Immunosuppressant drugs	WHODRUG GLOBAL B3 MARCH 1, 2025

ADCM

USUBJID	CMDECOD	CMPNCD	SDG01NAM	SDG02NAM	CQ01NAM
XXX-1001	METHYLPREDNISOLONE	00049601001	Corticosteroids	Immunosuppressant drugs	
XXX-1002	DIPHENHYDRAMINE HYDROCHLORIDE	00000402001		Immunosuppressant drugs	

Programming Approaches for SDGs/CDGs

Using Admiral to program SDGs:

```
sdg01 <- query(  
  prefix = "SDG01",  
  add_scope_num = TRUE,  
  id = auto,  
  definition = basket_select(  
    name = "Corticosteroids",  
    scope = "BROAD",  
    type = "sdg"  
  )  
)
```

```
admiral::create_query_data()
```

Programming Approaches for ACG to ADCM

Deriving drug group indicators in ADCM:

```
admiral::derive_vars_query()
```

Derives corresponding CDISC variables for each unique ACG PREFIX value:

- SDGzzNAM
- SDGzzCD
- SDGzzSC

Record-level matches are achieved by comparing TERMCHAR or TERMNUM from ACG to source variables in ADCM

ACG in Downstream Analysis

Using ACG in Intercurrent Event Analysis

Definitions for intercurrent events can vary by drug class or may be triggered by:

- Cumulative exposure
- Single-administration thresholds
- Specific duration of use

ACG allows for:

- Selective processing of relevant medications
- Accurate calculations of prednisone-equivalent dosing
- Alignment with protocol-defined event criteria

Case Study: Complex Drug Basket Derivations

Scenario: determine records classifying as protocol-prohibited medication

Prohibited medication basket #1:

- Drugs in both SDG01 and Custom Drug Grouping
- Drugs in SDG01 meeting certain conditions:
 - Route
 - Indication
 - Prednisone-equivalent dose/time criteria

Prohibited medication basket #2:

- Drugs in Custom Drug Grouping but not SDG01

Stepwise, ACG can be used to:

1. Identify drugs in SDG and CDG
2. Create drug grouping variables in ADCM
3. Flag drugs meeting basket conditions (ADCM)
4. Flag drugs needing prednisone-equivalent dosing calculations (ADCMSUM)

Case Study: Complex Drug Basket Derivations

ADCM

USUBJID	CMDECOD	CMPNCD	SDG01NAM	SDG02NAM	CQ01NAM
XXX-1001	METHYLPREDNIS OLONE	00049601001	Corticosteroids	Immunosuppressant drugs	

Prohibited medication basket #1:

- Drugs in both SDG02 and Custom Drug Grouping ❌
- Drugs in SDG01 meeting certain conditions:
 - Route ✓✓
 - Indication ✓
 - Prednisone-equivalent dose/time ?

Prohibited medication basket #2:

- Drugs in Custom Drug Grouping but not SDG02 ❌

ADCMSUM

USUBJID	CMDECOD	ADOSE	PARAM
XXX-1001	METHYLPRE DNISOLONE	5.2	
XXX-1001			Dose above X amount for at X consecutive days

Conclusion

1. **Consistency and Reproducibility:** Reduced reliance on free-text drug names, minimization of ad hoc programming, and less the risk of inconsistencies
2. **Protocol Alignment and Analytical Flexibility:** Intercurrent event definitions reflect protocol-specified rules while supporting study-specific nuances
3. **Reusability Across Trials:** Provides a reusable framework that can be adapted, facilitating traceability of drug classification logic from protocol to analysis.

Impact: ACG improves analytical consistency, reproducibility, and efficiency across trials, positioning it as a practical tool for robust and transparent concomitant medication evaluation in clinical research.

Thank you!

Contact:

Michelle Starkell

Hoffman-La Roche

michelle.starkell@roche.com