

# Coding Team Mergers: Challenges and Lessons Learned, So Far

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# Agenda

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- **Background**
    - **Company**
    - **Coding Group**
    - **Legacy Processes**
  - **Challenges/Critical Decisions**
    - **Coding Tools**
    - **Conventions**
    - **Review**
  - **Steps to integrated environment**
    - **Thesaurus Structure Today**
    - **Integration Activities**
    - **Lessons Learned**
    - **Positive Points**

# Background



**ZELBORAF<sup>™</sup>**  
(vemurafenib) tablets

**AVASTIN<sup>®</sup>**  
bevacizumab  
Reach beyond convention

**Tamiflu<sup>®</sup>**  
oseltamivir phosphate

**LUCENTIS<sup>®</sup>**  
RANIBIZUMAB INJECTION

**ACTEMRA<sup>®</sup>**  
tocilizumab

**Herceptin<sup>®</sup>**  
trastuzumab

**Xeloda<sup>®</sup>**  
capecitabine

**Valcyte<sup>®</sup>**  
valganciclovir HCl tablets  
and for oral solution

**CellCept<sup>®</sup>**  
(mycophenolate mofetil)

**Rituxan<sup>®</sup>**  
Rituximab

**FUZEON<sup>®</sup>**  
enfuvirtide

**KLONOPIN<sup>®</sup>**  
clonazepam

**PEGASYS<sup>®</sup>**  
(Peginterferon alfa-2a) FOR INJECTION

**KYTRIL<sup>®</sup>**  
granisetron HCl  
Tablets, Oral Solution & IV

**Pulmozyme<sup>®</sup>**  
dornase alfa INHALATION SOLUTION  
pulmozyme.com

**Xolair<sup>®</sup>**  
Omalizumab  
FOR SUBCUTANEOUS USE

**Nutropin<sup>®</sup>**  
[somatropin (rDNA origin) for injection]

**TNKase<sup>™</sup>**  
tenecteplase

**cathepsin<sup>®</sup>**  
ACTIVASE<sup>®</sup>  
(ALTEPLASE)  
THE ONE 2-ND 1-PA

**NEW Tarceva<sup>™</sup>**  
erlotinib  
tablets

3.4 nm

Sugar-phosphate backbone

# Company Background



## Roche

- One of the leading research focused healthcare groups with strengths in Pharmaceuticals and diagnostics
- Focus on personalized healthcare
- Therapeutic areas
  - Oncology
  - Inflammation
  - Virology
  - Metabolism
  - Central Nervous System
- Founded 1896, in Basel during Industrial revolution
- Over 80,000 employees worldwide

## Genentech

- Biotechnology company, manufacturing medicines that address significant unmet medical needs
- Therapeutic areas
  - Bio-oncology
  - Cardiology
  - Immunology
  - Ophthalmology
- Considered the founder of the biotechnology industry
- Founded 1976, South San Francisco
- 11,000 employees in United States
- Culture to work hard and to have fun!

# Thesaurus Group Background



## Roche and Genentech Legacy Conventions

- **Both Companies:**
  - Code 'globally' using the same coding conventions across all studies
  - Studies are coded consistently regardless of indication/study
  - Code out of context, terms must make medical sense standing alone
  - Coding ongoing basis, data reviews
  - MedDRA dictionary versioning

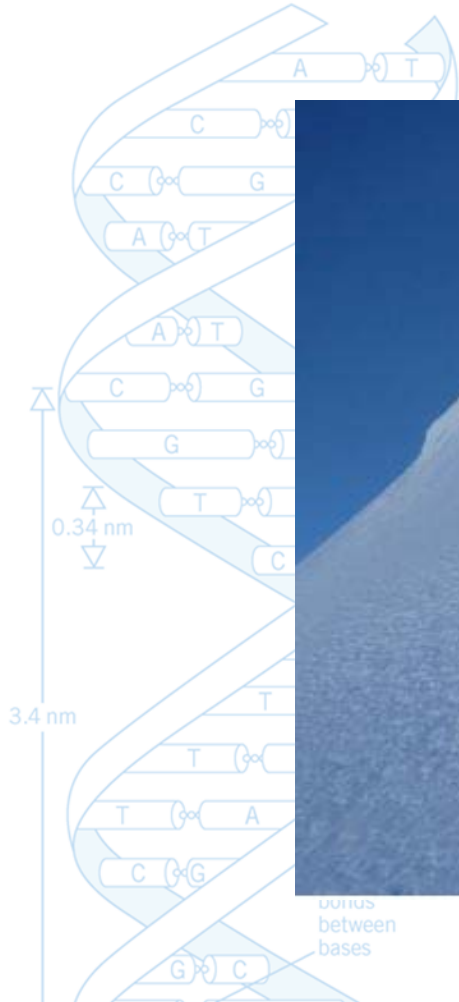
## Roche - Legacy

- **Two Thesaurus groups based in Welwyn, UK and Nutley, US**
  - Global Manager for two groups
  - Coding Manager in Nutley
  - 5 Clinical Coding Specialists, nurses/scientists
  - Drug Dictionary Manager - Pharmacist
  - Medical Dictionary Manager - Medic

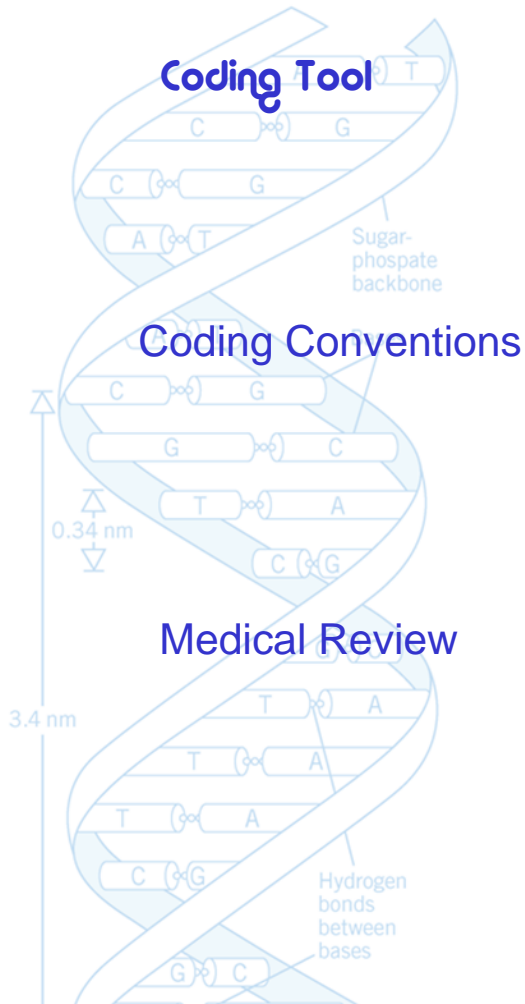
## Genentech - Legacy

- **Centralized Thesaurus group in South San Francisco**
  - Coding Manager
  - 5 Clinical Coding Specialists, nurses/pharmacist
  - TMS Business Process Role

# Challenges/Critical Decisions



# Challenges/Critical Decisions



- Both companies have their own tools
- Both companies have their own conventions
- Decision making process
- Structure for review process
- Decision making structure
  - Medical Dictionary Manager vs. Genentech approval process

# Legacy Coding Tools

## Roche

- In house Coding tool - Global Thesaurus (GThes)
- MedDRA For coding of medical events
- In-house Drug dictionary For coding of medications, procedures and investigations
- Specific screens available to be used at versioning
  - Allows review and re-linking of verbatim terms

## Genentech

- Oracle Thesaurus Management System (TMS) software, with custom functionality
- MedDRA For coding of medical events
- In-house Drug Dictionary For coding of medications, ability to add new medications/generic/classes
- TMS integrated with
  - RAVE
  - Drug Safety



# Challenges/Critical Decisions



## Coding Tool

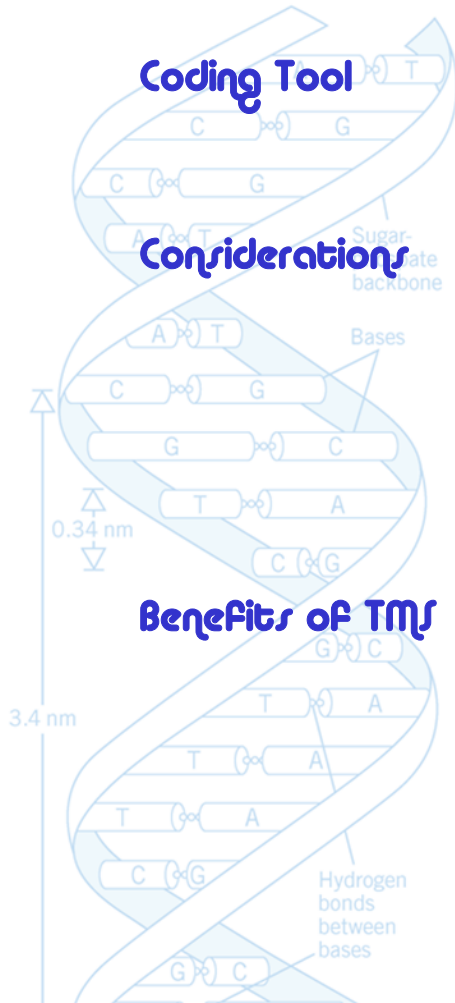
## Considerations

- Which tool do we use?
- What about synonyms?

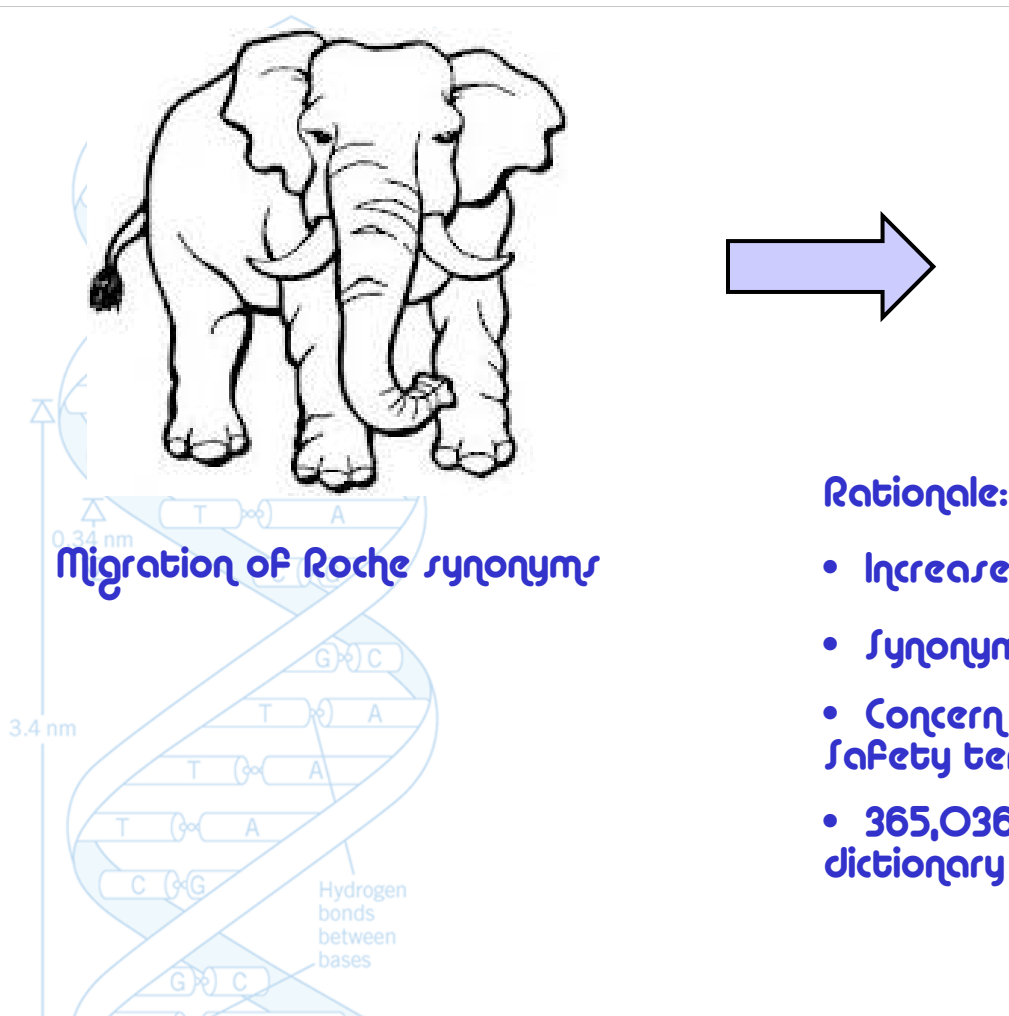
- Roche GThes Coding system becoming unstable
- No Oracle Support in house to update GThes
- Roche looking for a new tool
- Roche made decision to move to RAVE for future studies

## Benefits of TMS

- TMS linked to RAVE
- Integrated with new Drug Safety database
- Off the shelf tool
- Split action functionality
- TMS Business Process Manager in SSF



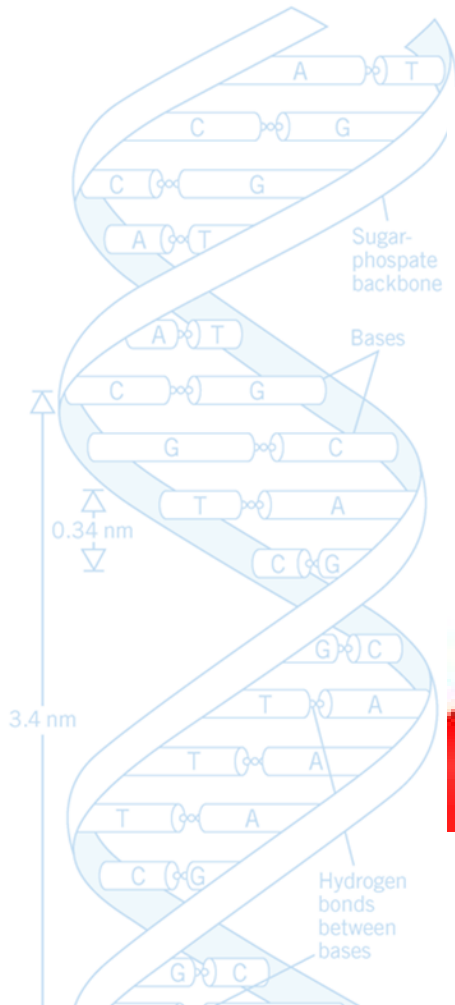
# Challenges/Critical Decisions - Migration of Synonyms



## Rationale:

- Increase auto-encoding rate going forward into TMs
- Synonym list in TMs much smaller
- Concern with change of process and an influx of safety terms
- 365,036 Roche synonyms migrated to MedDRA dictionary

# Challenges/Critical Decisions · Coding Conventions



# Challenges/Critical Decisions · Coding Conventions



Coding of "due to", "secondary to" and "related to" terms

Infectious terms that contain pathogen in description

*Term: Fever induced dehydration*

Roche · code to the MedDRA LLT of Fever

Genentech · query the site to report single medical concept

Going Forward: Split medical concepts for terms that contain a cause and effect reported description

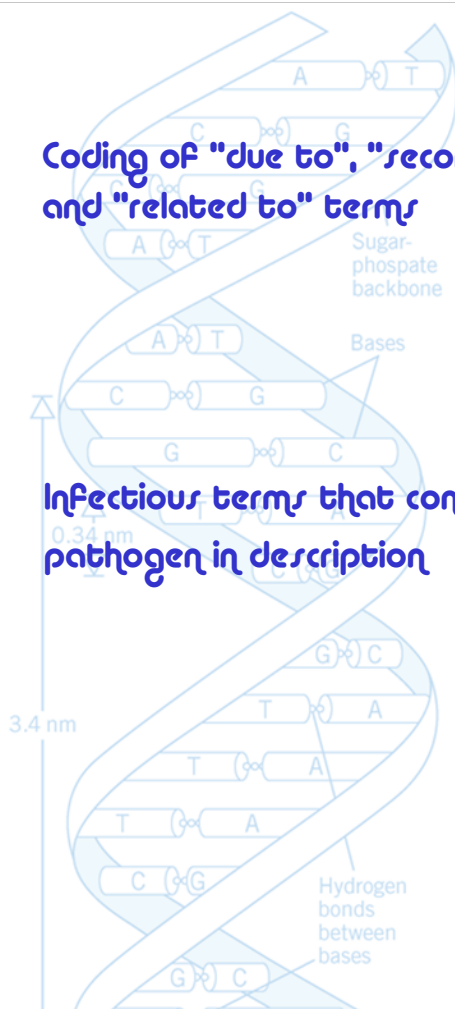
*Term: Infection of catheter with Staphylococcus*

Roche: Codes verbatim descriptions that specify a type of infection with organism to the organism

Genentech: Code verbatim descriptions to the type of infection

Going Forward: Code to the type or site of infection, not organism.

Pathogen can be captured elsewhere on form



# Challenges/Critical Decisions · Coding Conventions



Coding of verbatim terms reported with a diagnosis and accompanying signs/symptoms

Sugar-phosphate backbone

Bases

0.34 nm

Coding of lesion/lump/bumps

3.4 nm

Hydrogen bonds between bases

Term: *Food poisoning (diarrhea, vomiting)*

Roche · code to the MedDRA LLT of Food poisoning

Genentech - split term to single medical concept, or query, (depending on how term is reported)

Going Forward: code diagnosis/symptoms to diagnosis, if symptoms are cardinal symptoms of reported diagnosis. If symptoms are not typical for diagnosis, the term will be split.

Term: *Hepatic lesion*

Roche: Code, if MedDRA term, Query others

Genentech: Query all lesion terms

Going Forward: Query all lesion terms

# Solving Differences in Coding Conventions



## Global Thesaurus Steering Committee

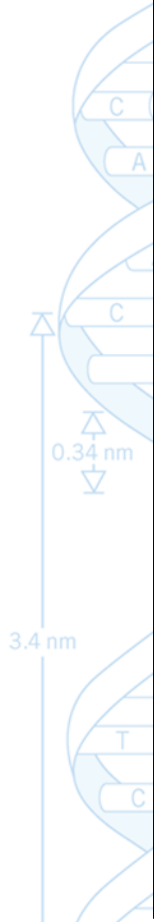
- Thesaurus directed
- Meets ad-hoc to discuss difficult terms/concepts Thesaurus is seeking input on. Creates consistency in coding
- Committee members include one/more representatives from
  - Thesaurus Management
  - Clinical Science
  - Clinical Operations
  - Drug Safety
  - Statistical Programmer Analyst
  - Biostatistics
  - Regulatory
- Decision maker for terms/concepts brought to committee

## Global Convention Group

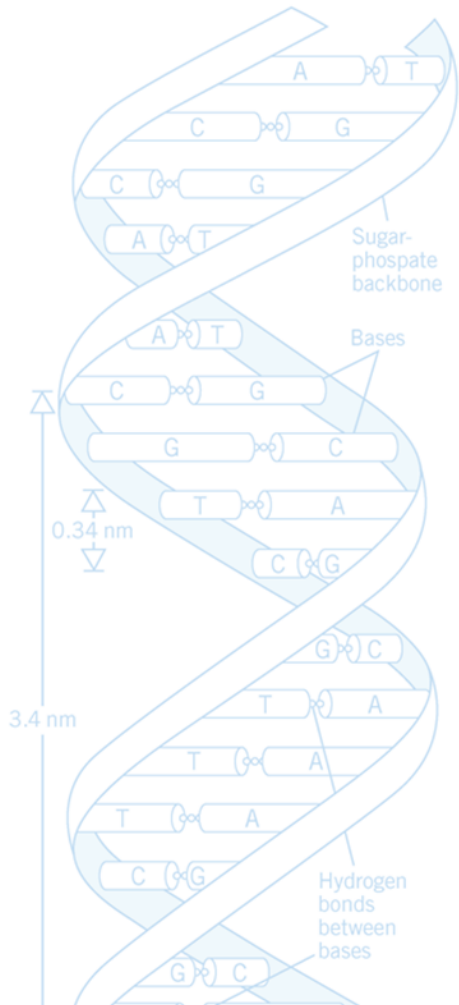
- Made up of representatives from all 3 sites
- Decides on Thesaurus convention when there are differing coding options
- From here can escalate term/concept to Global Thesaurus Steering Committee if necessary

## Terms of Special Interest

- Ad-hoc review of terms of special interest that need additional medical expertise
- Convene panel of experts to decide on terminology that has different interpretations and coding options i.e. squamous cell carcinoma/keratoacanthoma



# Medical Review



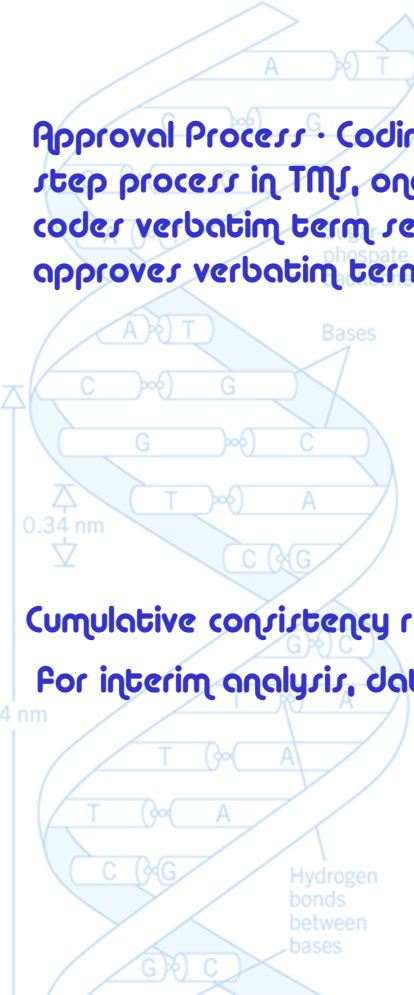
# Legacy Medical Review

## Roche

- Weekly MedDRA Review meeting
  - Medical Dictionary Manager or Thesaurus Manager reviewed
  - In conjunction Peer review
- Safety Coding reviewed daily by Dictionary Manager or designee
- Final decision maker - Dictionary Manager
- Ongoing review throughout study

## Genentech

- Two step coding process
  - Classify - one Thesaurus member classifies term
  - Approve - second Thesaurus member approves term
- Informative Notes Section in approvals - to leave comments i.e. suggest re-link, query, MISO request etc.
- Decision making - group consensus/additional input from clinical scientist as necessary
- Cumulative consistency review of terms in study for interim analysis, database locks
- Thesaurus Steering Committee for challenging terms/concepts needing cross functional input

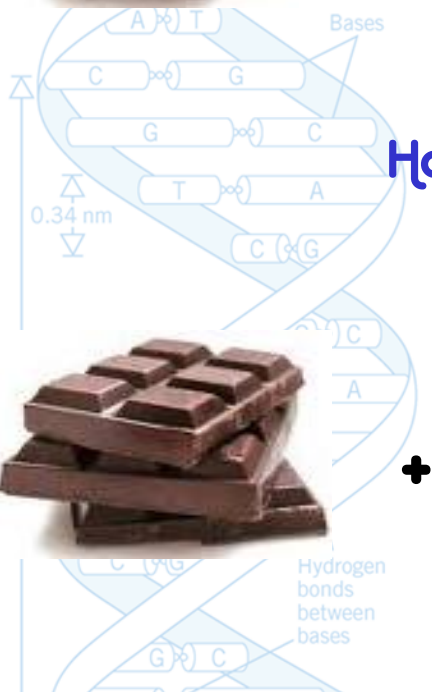
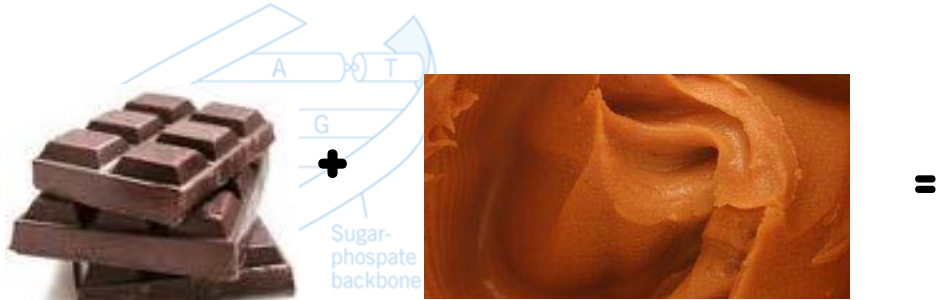


Approval Process - Coding is two-step process in TMS, one staff codes verbatim term second staff approves verbatim term

Cumulative consistency review - done  
For interim analysis, database locks

- Approval Pilot - global staff use informative note section to leave comments for suggestion, e.g. suggest different coding of verbatim term, inconsistencies in coding
  - All staff uses informative notes to communicate regarding verbatim terminology
  - New for Roche staff
  - Designated approval staff all sites
- 
- Review of unique verbatim terms reported in study
  - Typical to have two weeks to review and make changes
  - Have two or more members participate on review

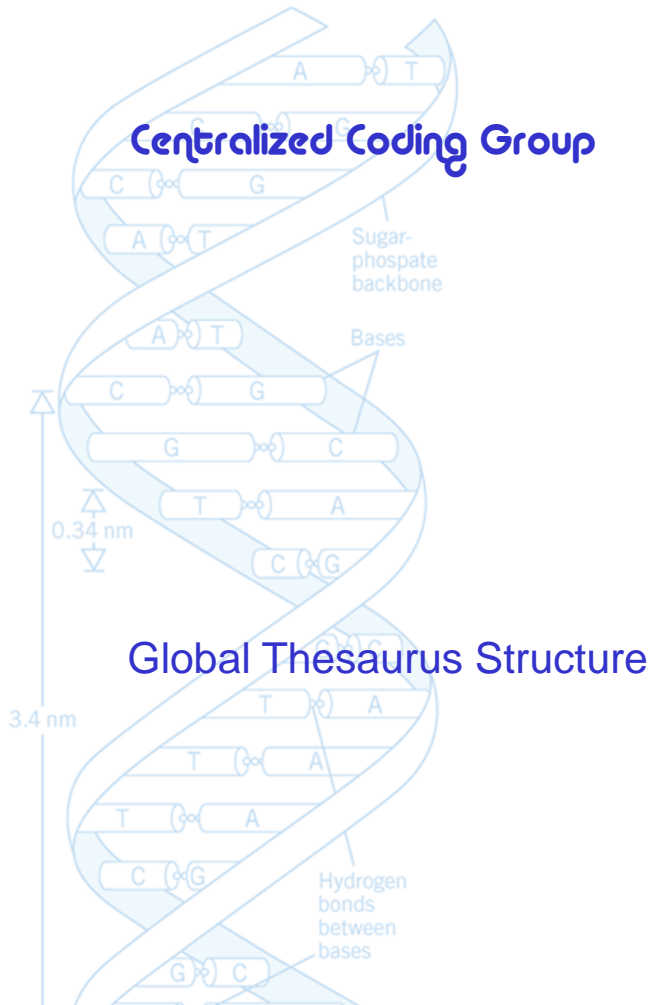
# Steps to Integrated Environment



How we get the best results globally



# Global Thesaurus Structure Today



- Three sites globally, Thesaurus Manager, each site
  - Welwyn, UK, 5 Thesaurus staff, Drug Dictionary Manager
  - Nutley, NJ, 5 Thesaurus staff
  - South San Francisco, CA, 6 Thesaurus staff
- Centralized Coding Model - code clinical and pharmacovigilance data
- Specialty group within Data Management
- Thesaurus Directed Groups
  - Global Thesaurus Coding Convention Group
  - Global Thesaurus Steering Committee

# Global Thesaurus Structure Today



- Thesaurus Management System (TMS) For coding with custom functionality
- Integrated with Rave, ARISg - For safety coding

- Training internal and external audiences
- Maintain partnership with TCS vendor and associates

# Integration Activities

## Roles/Responsibilities and Working Groups

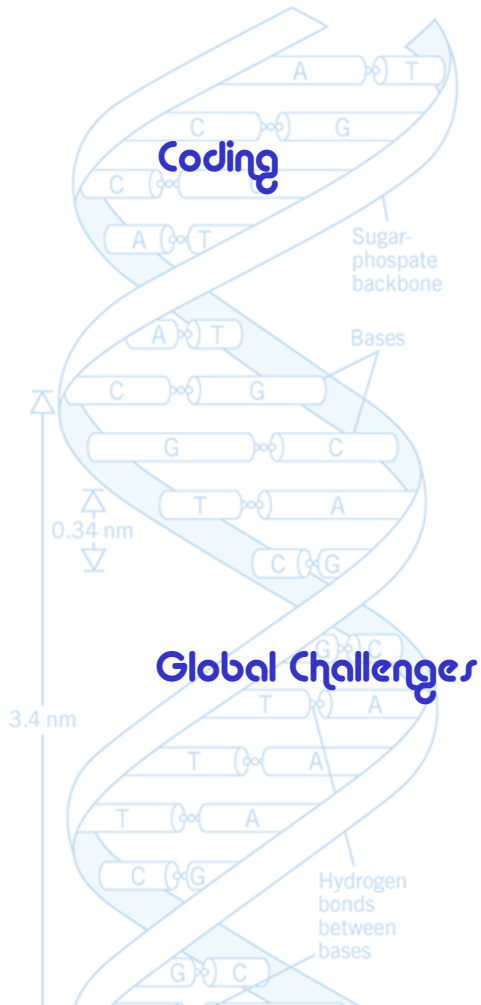
- Align job description/responsibility
  - Thesaurus part of core team to review job descriptions and give input
- Global Thesaurus Steering Committee - decisions on coding conventions
- Query Working Group - Format for query text based on TMS software
- Working Smarter Globally - eCRFs to code
- TMS Business Process Groups
- Drug Safety Integration Working Group
- Coding Policy For Thesaurus Group

## Integration Activities

- Training Thesaurus staff on software (Roche)
- New coding conventions
- Dictionary migration
  - MedDRA Dictionary
  - Drug Dictionary

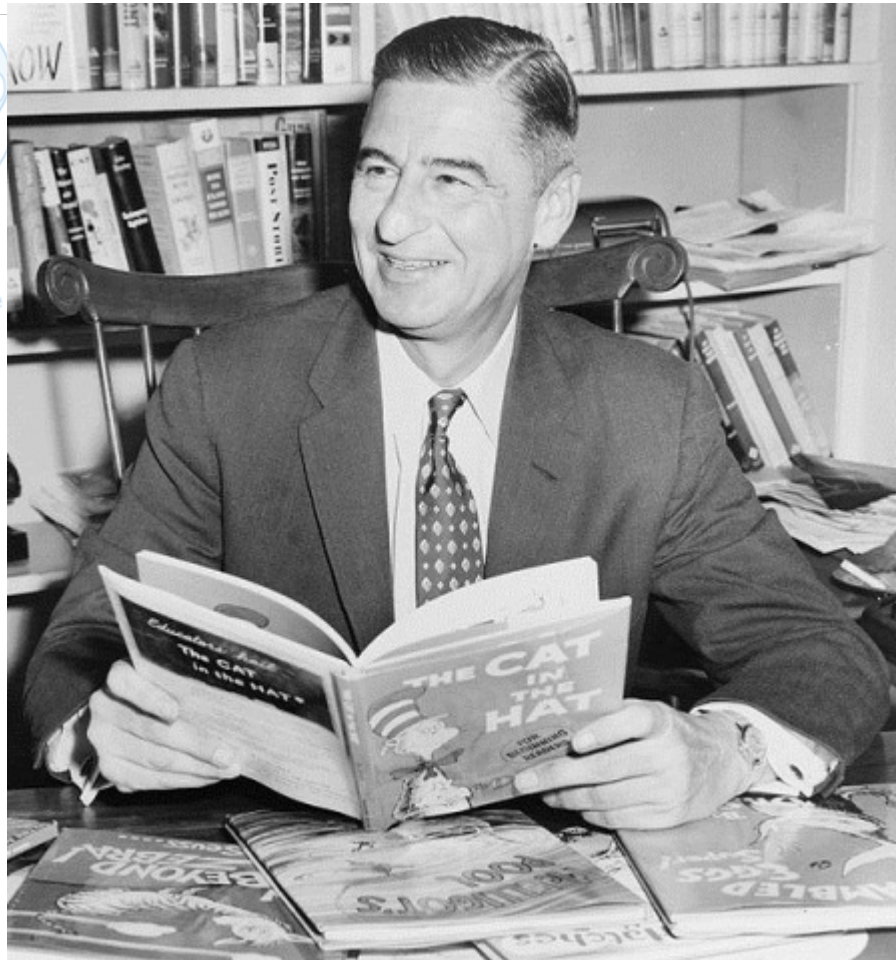
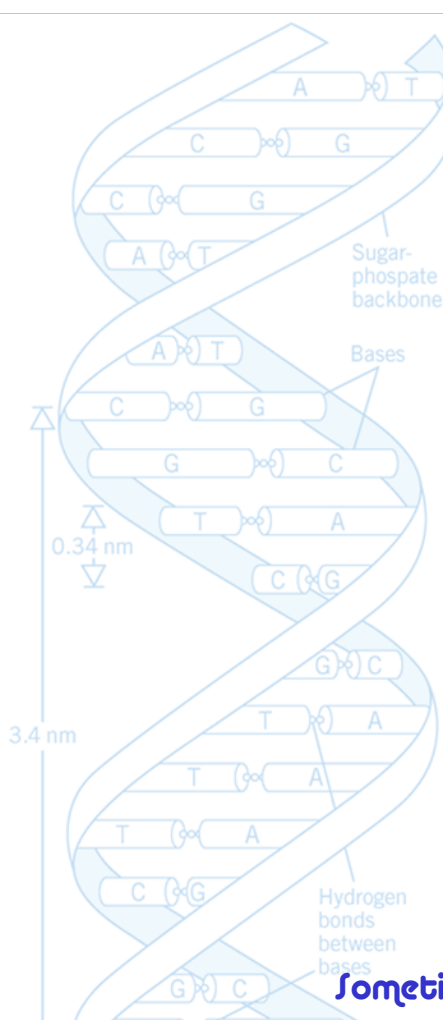


# Integration Activities · challenges



- TMS new For Roche
- Roche processes · continuing to support legacy studies/decommissioning GThes
- Evolving coding conventions
- Learning curve coding software/Rave
- Safety Coding - new processes
  
- Meeting times - early/late
- Communication/Team building
- Training vendor in new processes
- New SOPs, Guidance documents
- Resourcing - integration work and study work

# Lessons Learned



*Sometimes the questions are complicated and the answers are simple. Dr Seuss*

# Lessons Learned

## Decision Making

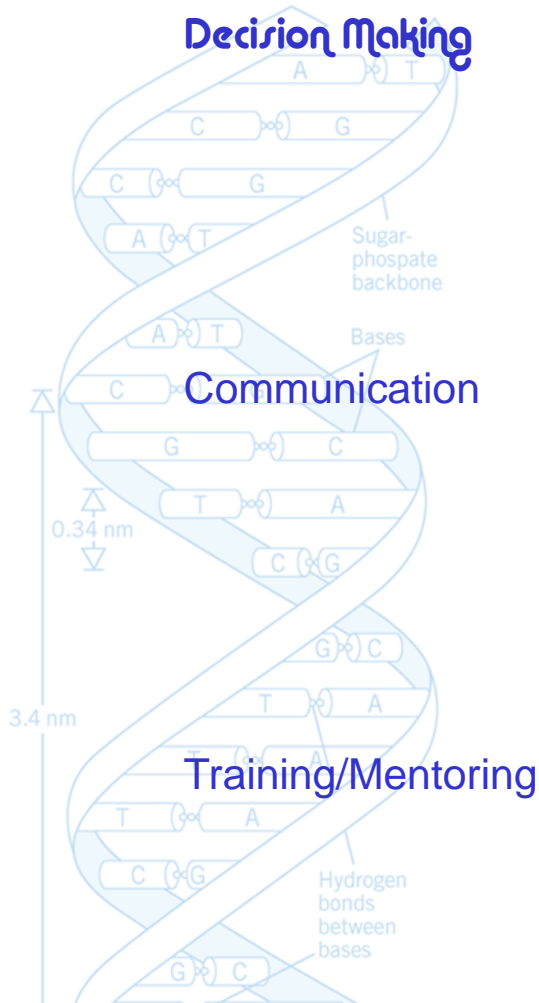
- Involve Thesaurus up front if a stakeholder
- Identify and involve stakeholders in Thesaurus processes, e.g. drug safety
- Make decisions best for business going forward

## Communication

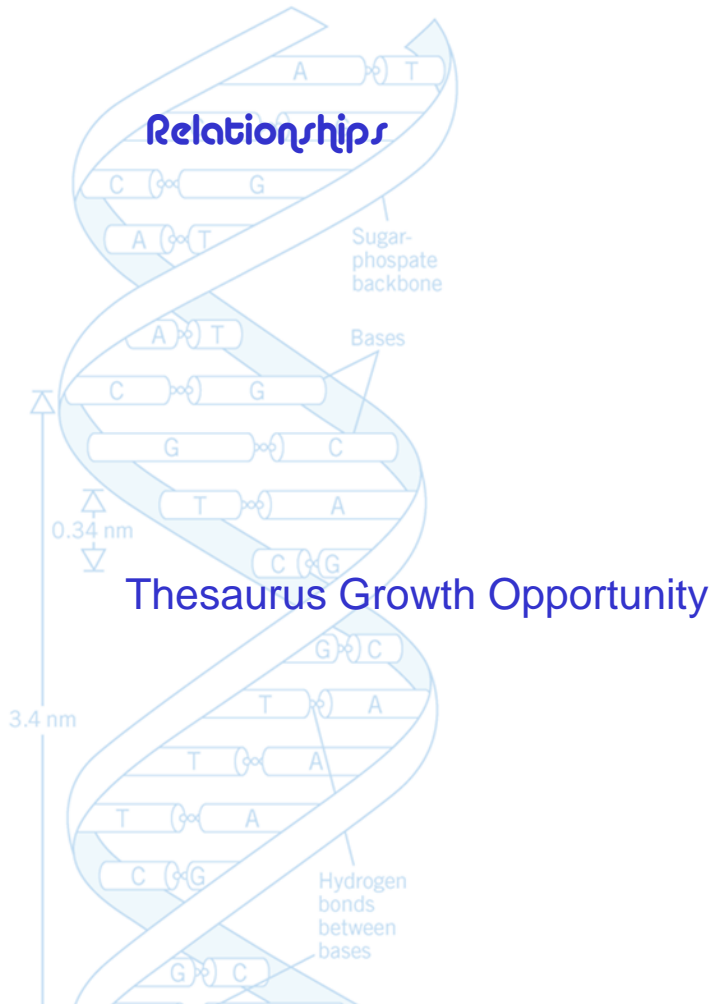
- Verbal over email
- New roles across company, need to know partners
- Increase interactions within Global group
- Face to face meeting – team identity

## Training/Mentoring

- Time to train staff on software/EDC
- Train and practice
- Mentorship for new processes



# Positives Points



- Increased profile of Thesaurus in global company
- Greater understanding importance of coding group
- More expertise within Global thesaurus group
- Thinking in a Global mind-set

- Increased participation Working Groups/Initiatives
- Learning new tools
- Increase opportunity to implement best practices

# Questions?

