Australian Government
Department of Health
Therapeutic Goods Administration

# Improved electronic submission methodologies

## Challenges and Future State

Ms Emma Richards
Assistant Director, Business Systems Review and Reporting Section,
Prescription Medicines Authorisation Branch, TGA

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Australian Government
Department of Health
Therapeutic Goods Administration

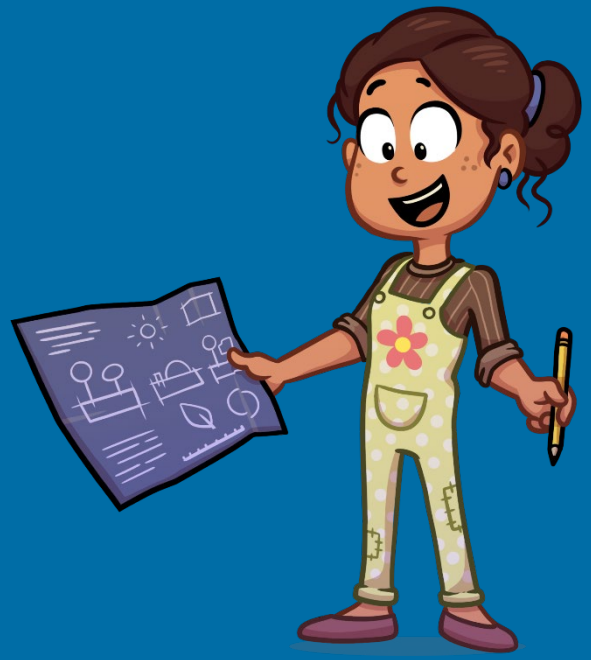
# QUESTIONS

## WHAT IS OUR GREATEST CHALLENGE IN THE ELECTRONIC DOSSIER MANAGEMENT SPACE?

## HOW ARE WE TACKLING THIS CHALLENGE?

# OUTLINE

- Define our greatest challenge
- Discuss how current work helps us tackle this challenge
- Look to the future



# GREATEST CHALLENGE

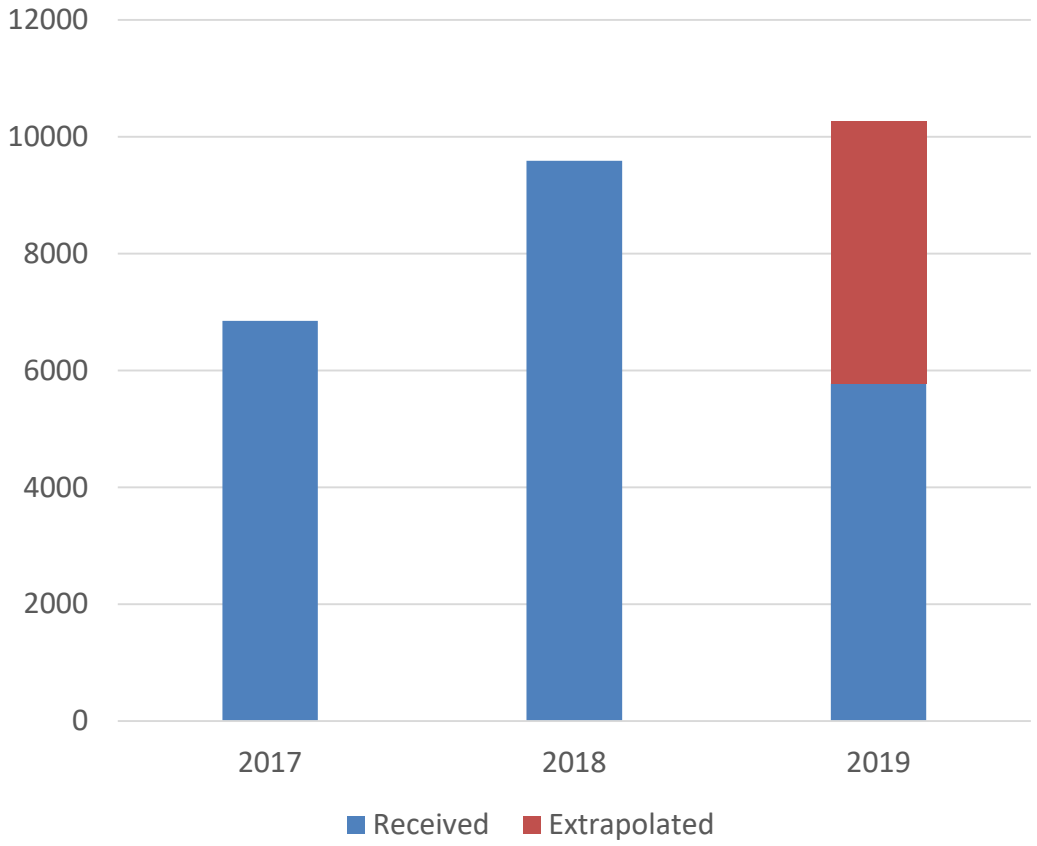
## WHAT IS OUR GREATEST CHALLENGE IN THE ELECTRONIC DOSSIER MANAGEMENT SPACE?

## DATA

**The greatest challenge we have is harnessing our data and presenting it in effective ways.**

# STATISTICS

## Total Number of Sequences Received per Year




- Number of sequences of data is increasing year on year
- In 2019 we are set to reach over 10,000 sequences

# GREATEST CHALLENGE

## To harness our data we need to understand:

- **WHAT** are the data requirements?
- **HOW** will we obtain and analyse the data?
- **WHY** should we do this?

# TACKLING THE CHALLENGE

## WHAT are the data requirements?

- IDENTIFY data needs
- ASSESS quality and suitability of current data sources

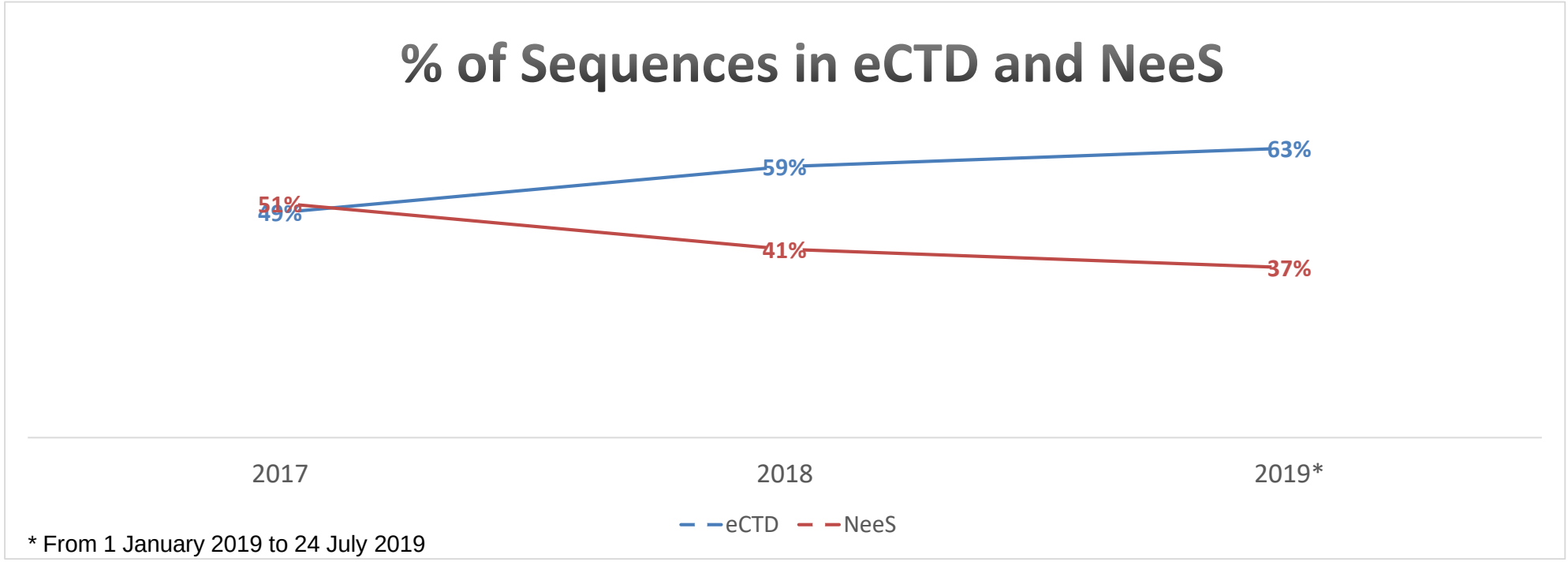
# TACKLING THE CHALLENGE

## HOW will we obtain and analyse the data?

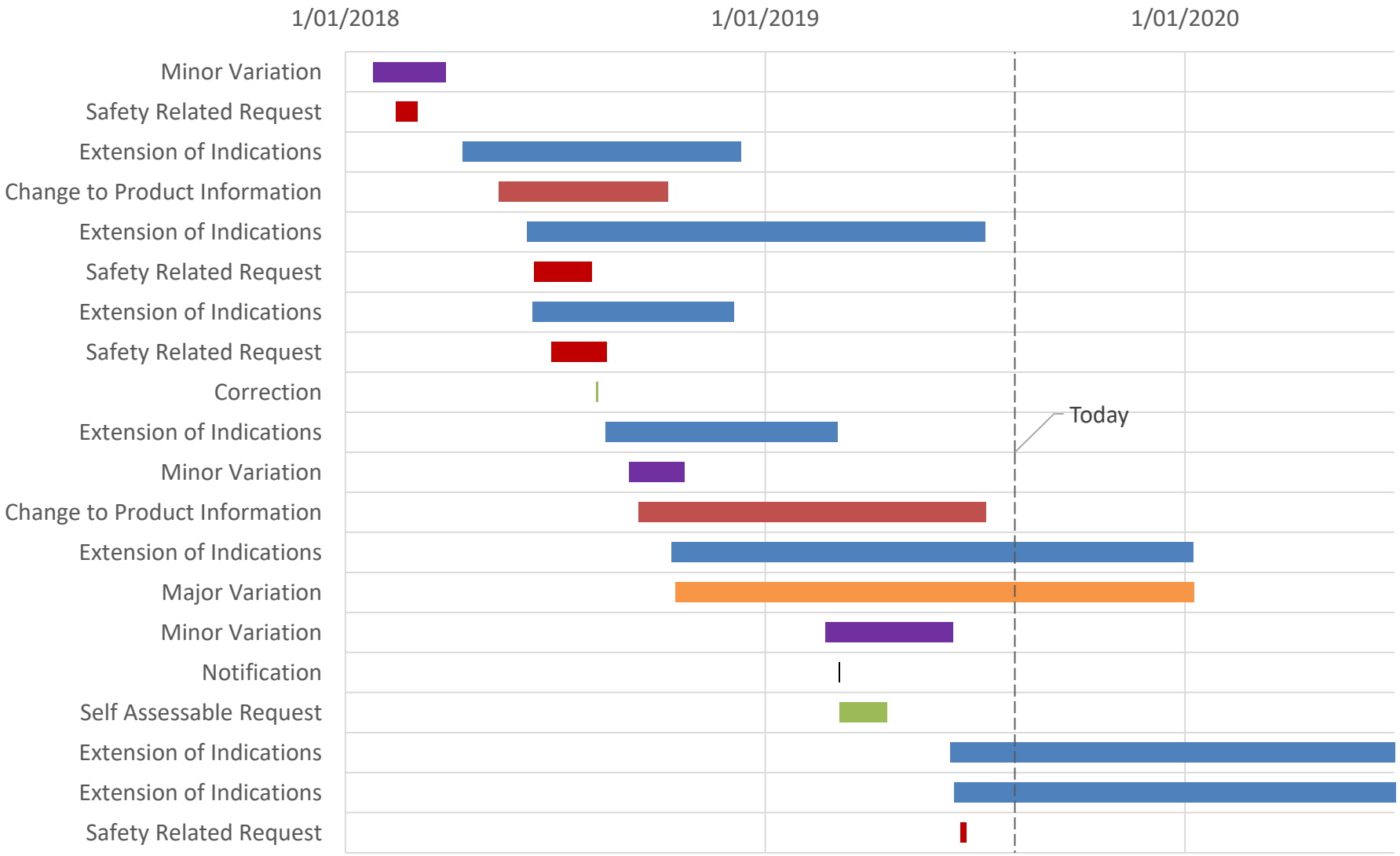
### PART A: Obtain the data

- Delivered in a TIMELY MANNER
  - Web gateway
  - Process automation
- STRUCTURE and FORMAT suited to analysis
  - eCTD
  - Greater use of XML
  - Specifications (regional and ICH)

# STATISTICS




* From 1 January 2019 to 24 July 2019

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# TACKLING THE CHALLENGE

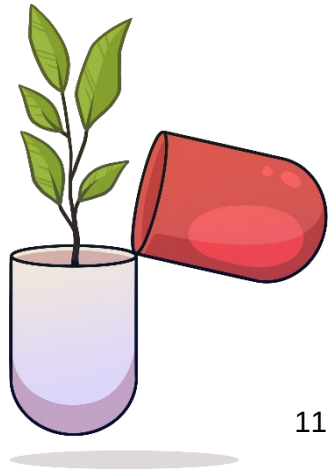
## HOW will we obtain and analyse the data?

### PART B: Analyse the data

- TECHNOLOGY
  - Artificial Intelligence (AI)
  - Deep Learning
  - Data visualisation programs
- LINKING the data
  - Determine the appropriate system for the data to be sourced

# TACKLING THE CHALLENGE

## WHY should we do this?



# TACKLING THE CHALLENGE

## Current State

# TACKLING THE CHALLENGE

## Planning

# TACKLING THE CHALLENGE

## Future State

# TACKLING THE CHALLENGE

## WHY should we do this?

- To better use available technology
- To easily see the full story of each medicine
- To assist with evaluations and post-market requirements

# TACKLING THE CHALLENGE

## WHY should we do this?

- To **BETTER USE** available technology
- To **EASILY SEE** the full story of each medicine
- To **ASSIST** with evaluations and post-market requirements

# TACKLING THE CHALLENGE

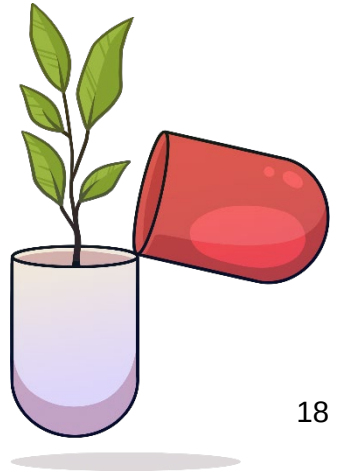
## WHY should we do this?

To draw meaningful insights to assist in ensuring the ongoing safety, efficacy and quality of medicines.

# LOOK TO THE FUTURE

## The Future of electronic submissions in Australia

- Utilises emerging technology
- Provides enhanced support for decision making
- Streamlines dossier processing



# LOOK TO THE FUTURE

## How can you help?

- Ask questions, provide suggestions
- Feedback on upcoming guidance and specifications
- Tidy up – look at transitioning to a single format with lifecycle history

# LOOK TO THE FUTURE

## How can you help?

- Plan your future gardens

**Contact edr@health.gov.au to discuss further.**

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