

# ramnog

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# Disclaimer

Views and opinions expressed are those of the speaker and not necessarily Novo Nordisk.

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- 01** What is HTA?
  - 02** What is AMNOG?
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  - 04** demo

# What is HTA?

# REGULATORY

*Do benefits  
outweigh risks?*

***Can*** we use the treatment?

*Is quality  
acceptable?*

# HTA

*Is it good value?*

*... for whom?*

***Should*** we use the treatment?

*Is it better than what  
we currently have?*

# REGULATORY

## Predictable

*Questions and trial designs agreed with regulators at an early point*

## Orderly

*ICH/regulatory guidelines anchor trial design, methods etc*

# HTA

## Dynamic

*Comparators change frequently within and across health systems*

## Messy

*Decisions cannot be postponed: use best available evidence (not always RCTs)*

# What is AMNOG?

# Arzneimittelmarkt-Neuordnungsgesetz .. or just AMNOG



Pharmaceuticals Market Reorganisation  
Act

Benefit assessment of drugs to the  
German market





## EU HTA

- Largely influenced by AMNOG.
- For all EU members.
- In effect from 2025/28/30

# Dissecting the AMNOG task



ramnog

# One framework for all AMNOG analysis

**$x + y > 1+1$**

**Reliable**

**Support workflow**

**Trustworthy**

**Fast enough**

**Easy to use**

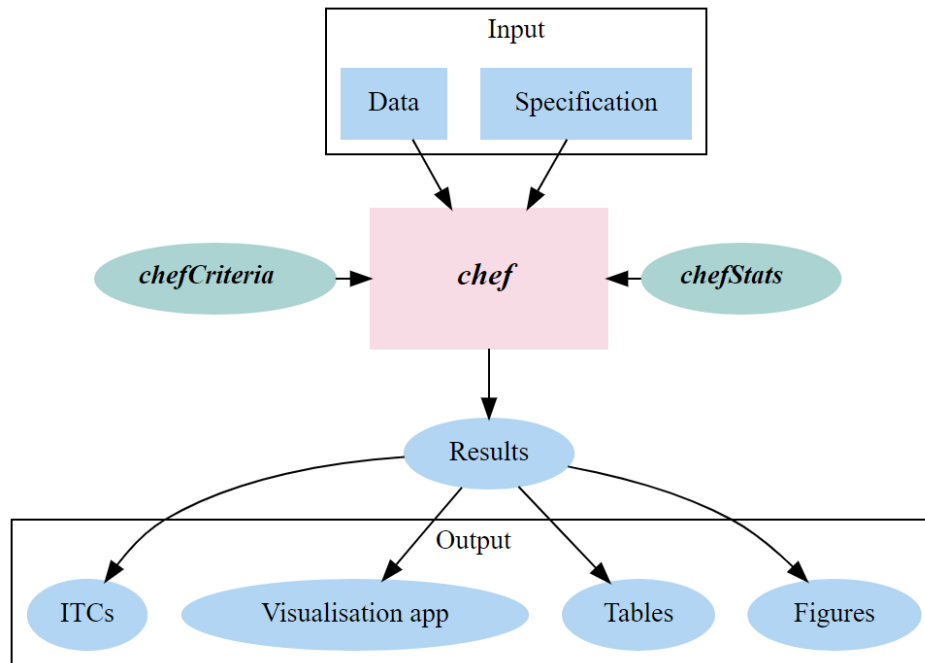
**Extendable**

**Replaceable**

# Support workflows

- **Iterative specification**
- **Manageable by one person**
- **No manual book-keeping**

# chef



## Modular



**Buildable**



**Extendable**



**Replaceable**

## Open source



**Collaboration**



**Quality**



**Trust**



**Sharing**

# Tech

**R**

**Data.table  
targets**

**Modular**

**Unit testing**

**Open source**

**Trusted, programmable**

**Fast, reliable, dependency tracking**

**Extendable, replaceable**

**Trust**

**OpenStatsWare – HTA-R  
MIT license**

# Results

## Happy users

### 3 submissions

- 50% reduction in time spent – with MVP
- Adhoc interface with SAS for modelling

**First project. Equivalent to 3300 CSR summaries. 90% done by chef.**



“All handled by a single person and it’s very manageable”



# Future work

- **Better support for statistical modelling**
- **Output templates**
- **Specification tool**
  
- **Collaboration**
- **CRAN**

# Demo

# Thank you!

<https://github.com/hta-pharma/ramnog/>

<https://github.com/hta-pharma/chef-example>

<https://openstatsware.org>

**Further information at R/Pharma and Phuse  
EU Connect (OS15)**