

# Securing the CAR-T-Cells supply chain management : Welcome to cognitive aids !

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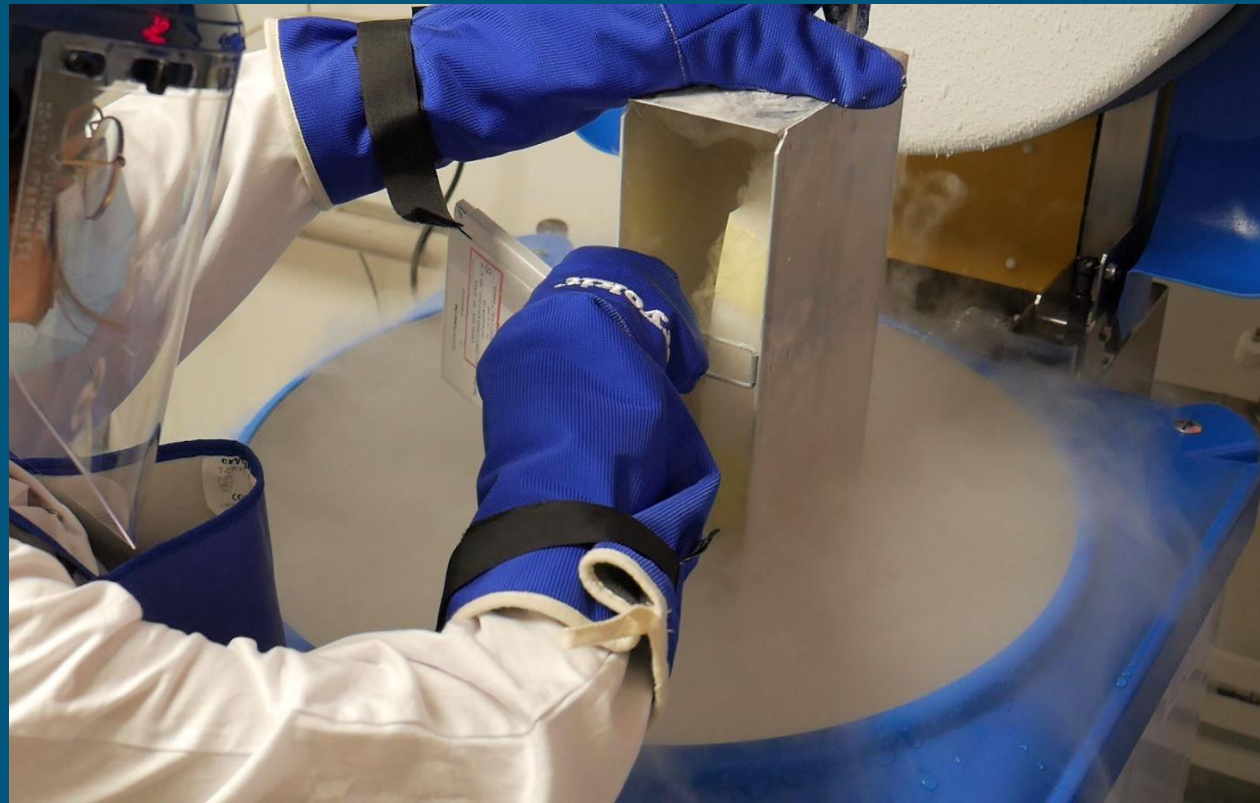
# Background

SAEs's contributing factors :

- Human factors and organization
- Cognitive biases (tunneling effect)
- Complicated situations, complex routines or unexpected urgent situations

SAEs related to  
healthcare products  
are the  
3rd leading cause  
of SAEs associated  
with healthcare \*

# CAR-T-Cells circuit



Long and complex medication system

Protocols requiring technical expertise

Specific regulation

# METHODS AND TOOLS USED TO SECURE THE CAR-T-CELLS CIRCUIT



# Documentary material analysis

Comparative advantages/disadvantages:

- Procedures
- Method operating
- Check-lists
- Decision trees
- Cognitive aids



**Cognitive aids : potential interest for the risk management strategy reducing mental workload in complex or high-risk situations**

# Cognitive aids

- Structured tool, easy to use
- Guides the operator step by step through the sequence of actions, guiding his reasoning
- Standardizes a process without omitting any steps
- Reduces the cognitive errors risk
- Paper or digital format

# MAX by Medae selection

- Customisable cognitive assistant
- Accessible via web platform or smartphone
- Login by nominative code
- Sequential protocol execution by step validation
- Publication of a final report at the end of the procedure, enabling statistical analysis after the event



**Fewer errors, less stress, improved crisis management,  
individual and team learning**

# Identification of sensitive circuit situations

Routine situations / Unexpected situations

Risk mapping analysis

Questionnaire : identifying the future users needs

Cross-analysis of protocols


Analysis of professional practices




# Preliminaries preparations before publishing cognitive aid

- Updating existing protocols
- Inclusion of incident management scenarios
- Selection of blocking steps in consensus
- MAX by Medae publishing documentation analysis

# RESULTS



# Editing a cognitive aid on MAX by Medae



- Customise digital algorithm
- To move from a tree structure to a sequence:  
define actions groups, which are steps dealing  
with the same theme
- Step validated to move for the next algorithm
- Chaining steps to ensure the right sequence in  
the field



# Steps in thumbnail format :

- Choice : binary response
- Message : informative or instruction
- List : check items
- Data entry : information gathering

The image displays four sequential screenshots of a mobile application interface, likely for a medical checklist. Each screenshot shows a different step in the process, with a common header area at the top of each screen.

**Common Header Elements:**

- Top bar: "MAX - Check-list 'réception des CAR-T-cells' - Profil..."
- Address bar: "https://player.medae.co/b59a0ccb6cd2d1973eba..."
- Navigation bar: "Référence inconnue", "Paramètres", a camera icon, and buttons for "Fin" and "+".
- Status bar: "Temps Global" and a timer.

**Step 1: Conteneur dry-shipper "coursier"**

- Buttons: "Quai de livraison", "Salle cryogénie"
- Text: "Le conteneur du dry-shipper du coursier est-il intègre (présence des scellés) et sans dommage ?"
- Buttons: "Oui", "Non"

**Step 2: Malette de transport**

- Buttons: "Salle de décongélation", "Livraison p"
- Text: "Transférer la poche dans la malette de transport"
- Button: "Valider"

**Step 3: Préparation du matériel**

- Buttons: "Préparation", "Quai de livraison"
- List of items with checkboxes:
  - ☐ Tenues : blouse manches longues et pantalon
  - ☐ Classeur patient
  - ☐ Badge, oxymètre
  - ☐ Chariot dédié au transport du dry-shipper du coursier
- Button: "Valider"

**Step 4: Heure ouverture dryshipper**

- Text: "Noter l'heure d'ouverture du dryshipper"
- Form: "Heure ouverture" with increment/decrement buttons for hours and minutes. The time shown is 13:15.
- Button: "Valider"



# 5 cognitive aids created

Check-list reception watch

Check-list reception

Check-list injection watch

Check-list preparation defrosting

Check-list defrosting

# Monitoring indicators and deployment

01

- Blank test with team manager
- Technical data validation

02

- Team communication
- MAX training

03

- Gradual deployment
- Monitoring indicators



# DISCUSSION CONCLUSION

**Documentary material analysis:** choosing the right documentary support to improve existing protocols, mastering all steps and ensuring safety

**Analysis of risk mapping and needs assessment:** define sensitive steps, involve operators, communicate on the project

**Select MAX:** customisable algorithm (integration of incident management scenarios)  
: traceability report for regulatory aspects and detailed analysis of practices (weak signals)

**MAX:** easy, intuitive editing, but it could be optimized  
: user-friendly: optimized ergonomic, easy to use



# Conclusion

Cognitive aids  
allowed to  
strengthen the  
security of the  
critical stages of  
CAR-T-cells

## High level of safety on risk management :

- Preventing cognitive bias
- *A priori* risk management : pre-publication preparatory phase
- *A posteriori* risk management : weak signals detected in the traceability report

**MAX by Medae** : innovative, easy-to-use and intuitive tool

**Times saved in traceability**

**Harmonization of practices**

**Extend the approach** to other PUI areas



THANK YOU FOR YOUR  
ATTENTION