GERPAC oral communication

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

STASSAERT E, DESQUINES R, DUQUESNE J, GASTAUT N, BAAZIZ H, CAMPODONICO C, RUITORT S, COLLOMP R

CHU de Nice: Hôpital Archet, 160 Ch St Antoine de Ginestière, 06200 Nice, FRANCE

Background

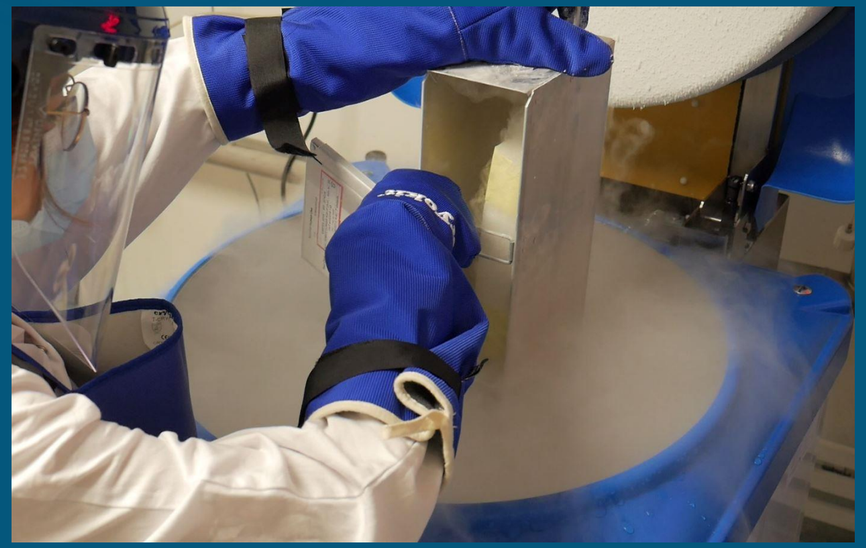
SAEs's contributing factors :

- 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 *

* HAS annual report on SAEs and ENEIS 3 study

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

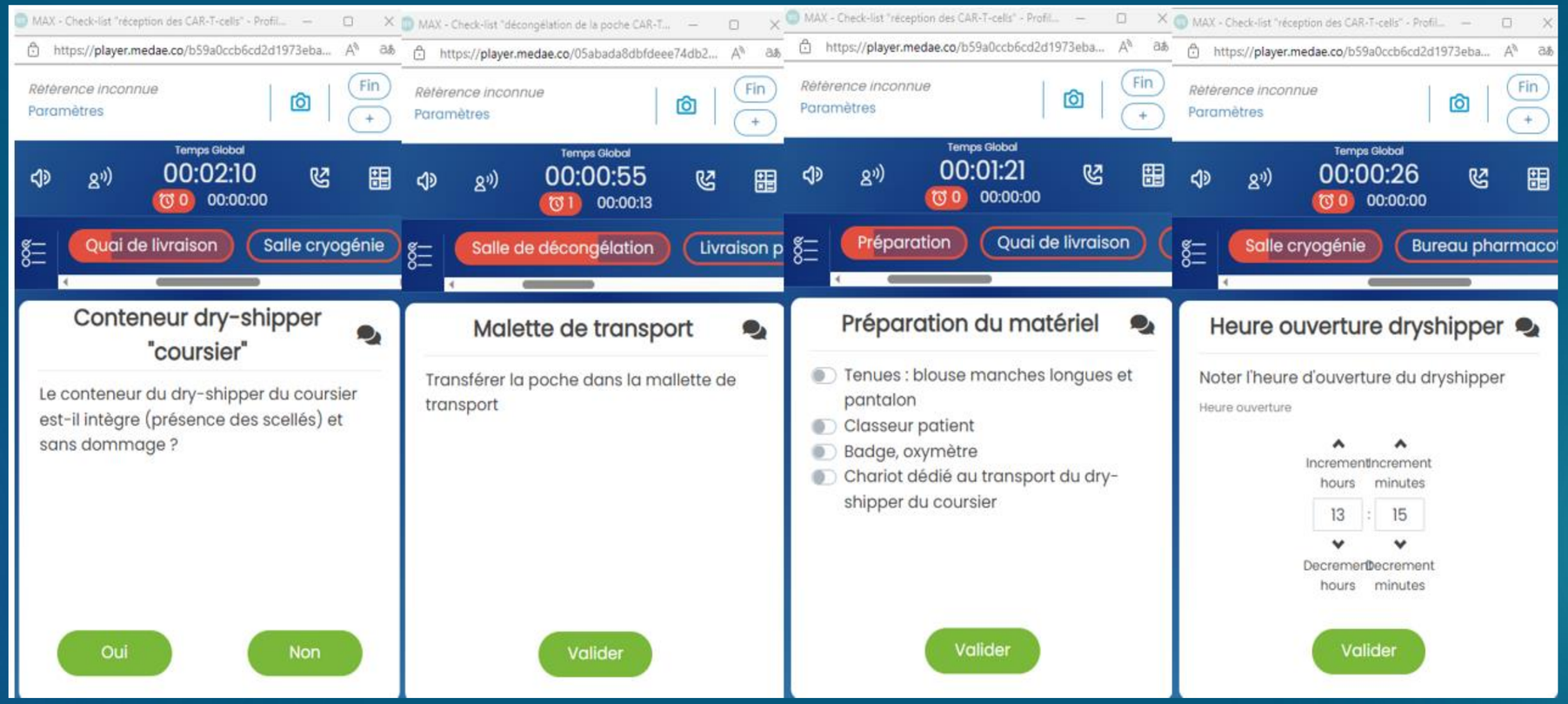
RESULTS

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



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

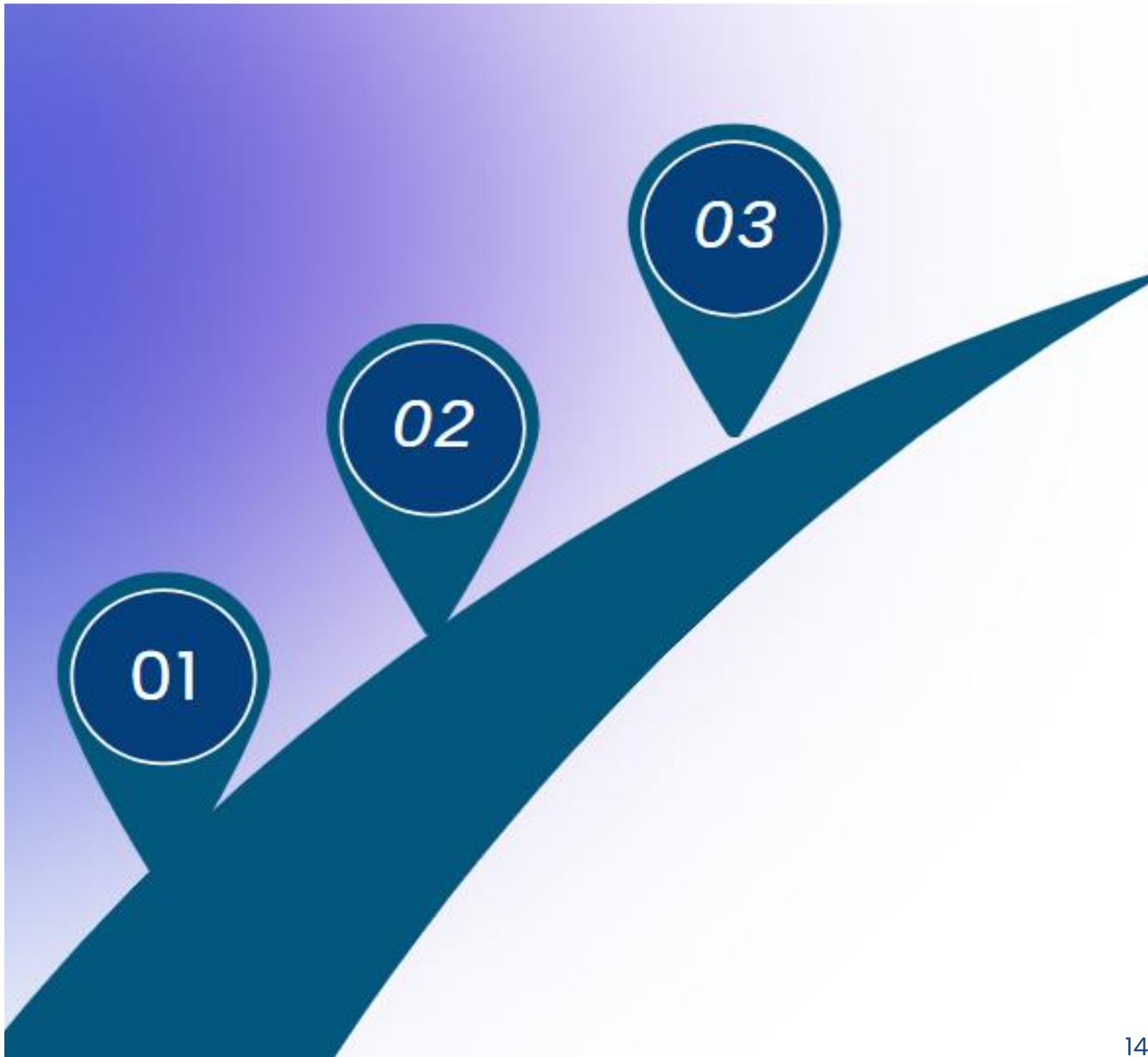
- Blank test with team manager
- Technical data validation

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