Sciences de la Vie

AFSSI

Association Française
des Sociétés de Services et d'Innovation

Centre de recherche
FRANCAIS

afssi.fr

Les **membres AFSSI** ont la **parole**

WEBINAIRE

Le partenaire incontournable de **vos innovations**

Proche de chez vous

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PPRS Research

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NOTRE ACTIVITÉ

Conseil et développement de médicaments et de solutions innovantes dans le domaine du sommeil et des pathologies du système nerveux central

Science & Technology

Independent company

Founded in 2010

Locations

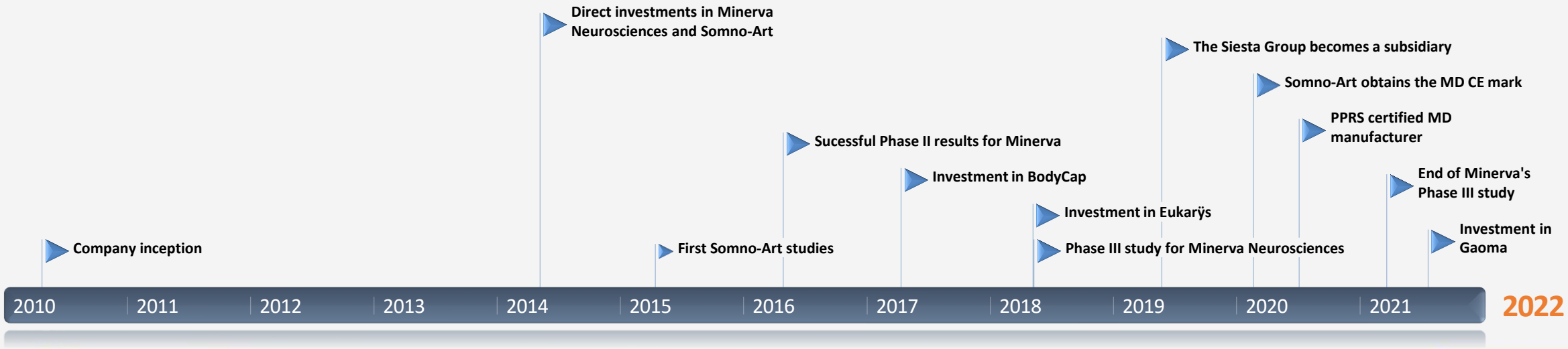
France, Austria and the US

Strong know-how in Central Nervous System (CNS)

Broad experts network

Unique business model

Long-term partnering towards success in drug / medical device development



Capabilities & achievements

700+
(Pre)Clinical studies
in 6 major therapeutic areas

150+
Drug Candidates
at various development stage

100+
Publications
in major scientific journals

5
Investments
in pharmaceutical and medical device companies

2
Medical Devices
2 CE-marked

25+ years in accompanying CNS drugs

PhDs, MDs, PharmDs and MScs in Neurosciences, Life Sciences, Natural and Computer Sciences, Electrophysiologists

15+ years in Corporate Development

PharmD, PhDs, Finance and Business degrees

10+ years in developing medical device and algorithms

MDs, PhDs Neuroscientists and Software Engineers (machine learning)

International partnering network

Hospitals

Academic research centers

Key Opinion Leaders

Investigative clinical trial sites

Biopharmaceutical companies

Biotechnology companies

Clinical Research Organizations

Startups

Venture Capital

PPRS & The Siesta Group 2019

PPRS
THE STRATEGIC PARTNERING ORGANIZATION

Drug development R&D services / Due diligence

Medical Device / AI development capabilities

Investments cash & in-kind

THE siesta GROUP

Service provider for clinical trials in CNS

Experts in EEG, PSG and actigraphic measurements, data analysis and algorithmic development

Unique central scoring approach

Therapeutic Areas & Expertise

Our track record includes the development support of therapeutic drugs from discovery to NDA stage

Consulting and Strategy in Drug Development

We partner to drive our clients' drug development project toward success

Offers & Expertise

We partner to drive our clients' drug development project toward success

Drug Development

Translational and early-stage focus on target validation to enhance chance of success

Expertise with small and large molecules

Expertise in formulations (oral, liquid, intranasal…)

Backed-up by non-clinical, clinical, operational and regulatory know-hows

AI & Medical Devices

Algorithms and wearables medical device development focus

Optimize clinical trials and drug safety/efficacy through digital biomarkers

Business strategy

Leveraging scientific expertise for smart & early investments

Increasing success rate of early stage development plans

Drug Development Team

NADINE NOËL

Drug Development Director

EMMANUELLE GEORGI

Head of CSM

CMC Project Manager

CMC activities

SANDRA WERNER

Head of Non-Clinical

CMC Project Manager

Non-clinical development

FLORENT SCHMITT

Non-Clinical Project Manager

FRANÇOISE RICHARD

Non-Clinical Project Manager

OLIVIER GILLARDEAUX

Toxicology Expert Project Manager

CMC activities: Drug Substance and Drug Product

Know-How & Expertises

- Strong experience in Synthesis of NCE and large molecules
- Strong experience in DP manufacturing with complex formulations (modified-release, intranasal, sterile)
- Very good knowledge of regulatory needs at each step of development
- Risk management

Management

- Management of programs from discovery to late phases
- Development plan design & optimization taking into account the sponsor's strategy
- Budget planning & monitoring
- Customer reporting

Operational aspects

- CDMO identification and selection
- Management of regular audits
- Management and coordination of development programs with CDMOs including R&D, analytics, stabilities, manufacturing campaigns…
- Review and approval of protocols & reports
- Drug Supply overseeing during clinical trials

Regulatory Support

- Ensure GMP compliance
- Define target product profile & regulatory strategy
- Preparation & maintenance of the regulatory documents (IMPD, IND Module 3, briefing package…)
- Interactions with Regulatory Authorities (EU/US) including during clinical trials
- Participation to CMC meetings (EU/US)

Non-Clinical activities

Know-How & Expertises

- Drug discovery & lead selection
- Pharmacology, Toxicology, DMPK, Bioanalytics…
- Expertise in Pharmacokinetics
- Gap analysis/due diligence
- Risk management
- Regulatory & scientific watch

Management

- Design of development plan (road-map) adapted to clinical needs and company strategy
- Large network of CROs
- Network of experts for specific questions
- Budget planning & monitoring
- Customer reporting

Operational aspects

- CRO identification and selection
- Management of regular audits
- Direct management of the CROs including proposals and study execution
- Review and approval of protocols & reports
- Maintenance of the documentation/data room

Regulatory Support

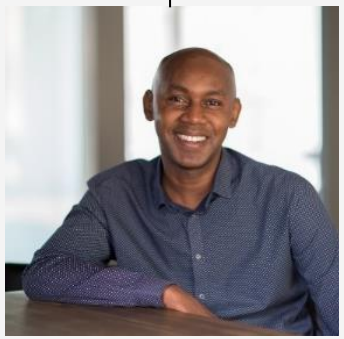
- Ensure ICH/GLP compliance for all activities
- Writing of regulatory documents (IB, IND, briefing package…)
- Participation to meetings with Regulatory Authorities (EU/US)

Clinical Operations and Medical Teams

ELISABETH LUTHRINGER
Director of Clinical Operations

CORINNE STANER
Chief Medical Officer

FAROUK AIAD
Clinical Study Manager



ERIC NTWALI
Clinical Study Manager

ALLISON GARCIA
Clinical Study Manager

MARIE-LAURENCE GOURLAY-CHU
Clinical Research Physician

Study Start-Up Activities

Development of study documentation

- Synopsis
- Protocol:
  - ↳ *Elaboration of the study design and protocol*
- Investigator Brochure
- IMPD
- Inform Consent Form
- Project Management plan
- Risk Management plan
- Monitoring & Medical Monitoring plan
- Data Management plan
- Statistical Analysis Plan
- Electronic Case Report Form completion guidelines
- Trial Master File plan

CRO Selection

- CRO identification
- BID Defense meeting

Sites Selection

- Study feasability
- Sites identification
- Sites qualification

Project Management

- Budgets evaluation
- Timelines
- Study team kick-off meeting
- Investigator meeting
- Sites initiation
- Regulatory Support

From study conduct to Clinical Study Report publication

Study conduct

Trial implementation - First Subject First Visit → Last Subject Last Visit - Final report

- Project management
- CRO and Vendor management
- IMP Supply
- Trial Master File Maintenance
- Site management and monitoring
- Screening and Enrollment follow-up
- Data collection and data review
- Sites close-out
- Corrective And Preventive Actions
- Database Lock
- Bioanalytics
- Clinical Study Report

Track Record

INDICATION	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA SUBMISSION
Narcolepsy						
Gene therapy						
Parkinson's disease						
Epilepsy						
Pain						
Depressive disorder						
Insomnia						
Hepatitis B						
NASH						
Schizophrenia						

Case study: Minerva Neurosciences

BACKGROUND

Initially PPRS was the development arm of 3 start-up companies Cyrenaic, Sonkei and Mind-NRG in an asset centric model.

In 2014: merging of these 3 companies and licensing of a Janssen's compound for an IPO to create Minerva Neurosciences. Direct investment of PPRS for the IPO.

MISSIONS

Support Minerva for the development strategy of all compounds in the pipeline, to bring them to late clinical stage / registration in accordance with regulatory requirements

ACHIEVEMENTS

- Drug substance: synthesis development from phase 1 to commercial batches
- Drug product: development of immediate, slow-release and delayed-release formulations and management from phase 1 to commercial batches
- Pre-clinical regulatory studies oversight
- Management of clinical phase I, II and III studies
- Support for FDA and EMA meetings
- Support for regulatory documents including IMPD, IB, IND, PSP/PIP and NDA package preparation
- Research and development of new families of compounds
- Support for patents

Case study: drug development in Parkinson's disease

BACKGROUND

PPRS has a proven track record about drug development in CNS in general and in neurodegenerative diseases in particular.

Several early stage products in our clients' portfolio were targeted to PD.

MISSIONS

Several compounds (NCE or Biologics) at pre-clinical stages with different MoA were screened in PD models using different approaches.

ACHIEVEMENTS

- Good knowledge of CROs offering PD models → the screening is targeted to the best suited
- Use of several *in vitro* and *in vivo* (mice, rats and monkeys) models: e.g. MPP+, 6-OHDA , rotenone or alpha-synuclein injuries with different endpoint evaluations like TH cells survival or inflammatory evaluation
- Participation to a European consortium under Horizon 2020 (PRIMOMED):
  - ✓ Use of primate models to support translational medicine and advance disease modifying therapies for unmet medical needs
  - ✓ Follow-up of PD clinical scales, locomotor activity, sleep analysis and inflammatory components
- Writing and submission of grant applications to MJFF

PPRS: 5 points clés à retenir

- Expertise translationnelle depuis le discovery jusqu'au étapes tardives du développement
- Couvre toutes les activités du développement de médicaments
- Large réseau de prestataires et de consultants
- Partenariat stratégique pour augmenter les chances de succès
- Investissements dans des projets early-stage

Development of innovative solutions in sleep medicine

PPRS – Activités Dispositifs Médicaux

- Depuis 2020, PPRS est certifié fabricant de dispositifs médicaux, et regroupe toutes les fonctions nécessaires pour le développement, la certification et la commercialisation de dispositifs médicaux :
  - En interne, avec une équipe de 12 personnes
  - En partenariat avec 1 université, 1 CIC, 1 CHU et 5 PME
- Des équipes de développement composées d'experts dans le système nerveux central et périphérique; de médecins; d'ingénieurs en algorithme, logiciel embarqué, électronique, mécanique, textile
- Une équipe d'opération clinique pour organiser et collecter les données cliniques
- Une équipe qualité et réglementaire assurant des développements dans le respect des dernières normes européennes et américaines
- Des équipe opérationnelle et de vente pour distribuer les solutions sur les marchés de la recherche clinique et du médical

Somno-Art – le premier DM PPRS (1)

- À ce jour, il n'existe aucune offre validée cliniquement entre la polysomnographie de référence (en milieu hospitalier, coûteuse en temps et en argent, stressante) et l'actimètre.
- Nous avons développé un système alternatif : Somno-Art, composé d'un dispositif médical ambulatoire qui capture les données physiologiques du patient et un logiciel, générant des rapports de sommeil exploitable par le médecin
- Le dispositif est marqué CE depuis 2021
- 2 publications sur les performances du logiciel sont disponibles, et 2 nouvelles publications sont en cours de revue

Somno-Art – le premier DM PPRS (2)

Somno-Art – le premier DM PPRS (3)

SOMNO-ART SOFTWARE

Our IT architecture has been developed in order to automate the sleep data analysis process, ensure secure data transfer throughout the whole process, and to be compliant with all the regulations.

1. RECORDING

Sleep data are recorded by Somno-Art Device and transferred to the PC

2. DATA TRANSMISSION

The night data is securely sent to the Somno-Art data center

3. SCORING

Once validated, the night data is scored by Somno-Art Software

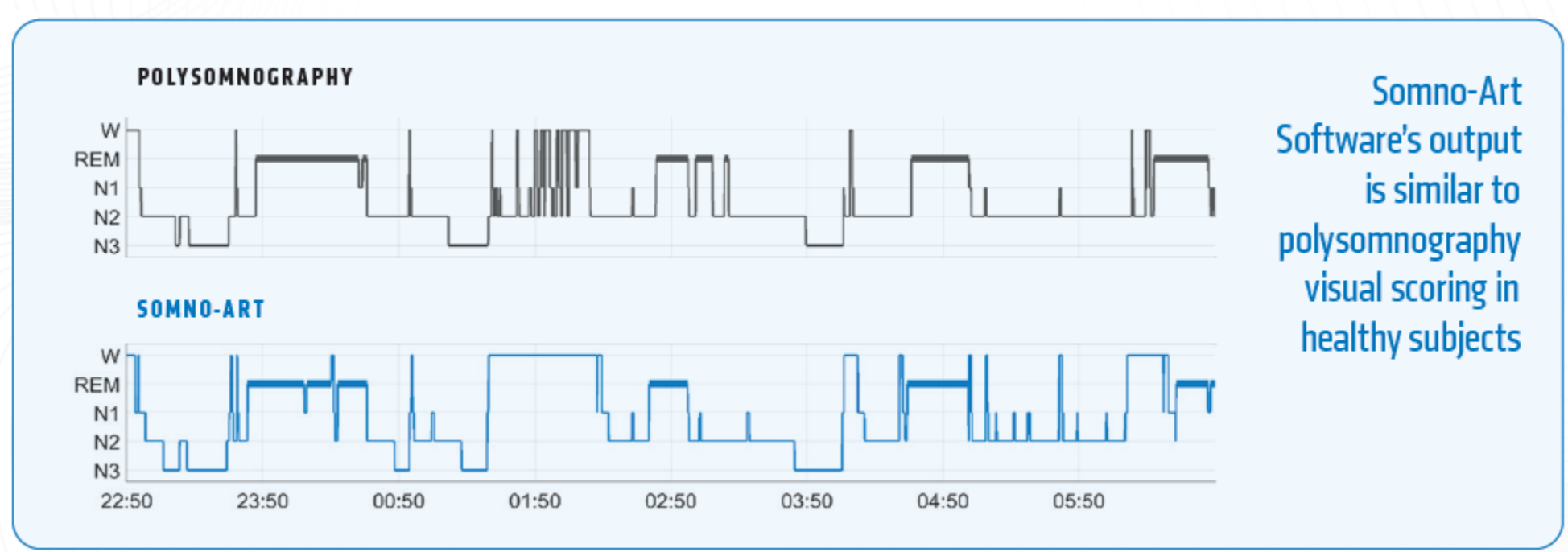
4. REPORT CREATION

For each night a sleep report is created, containing all the information recommended by the AASM

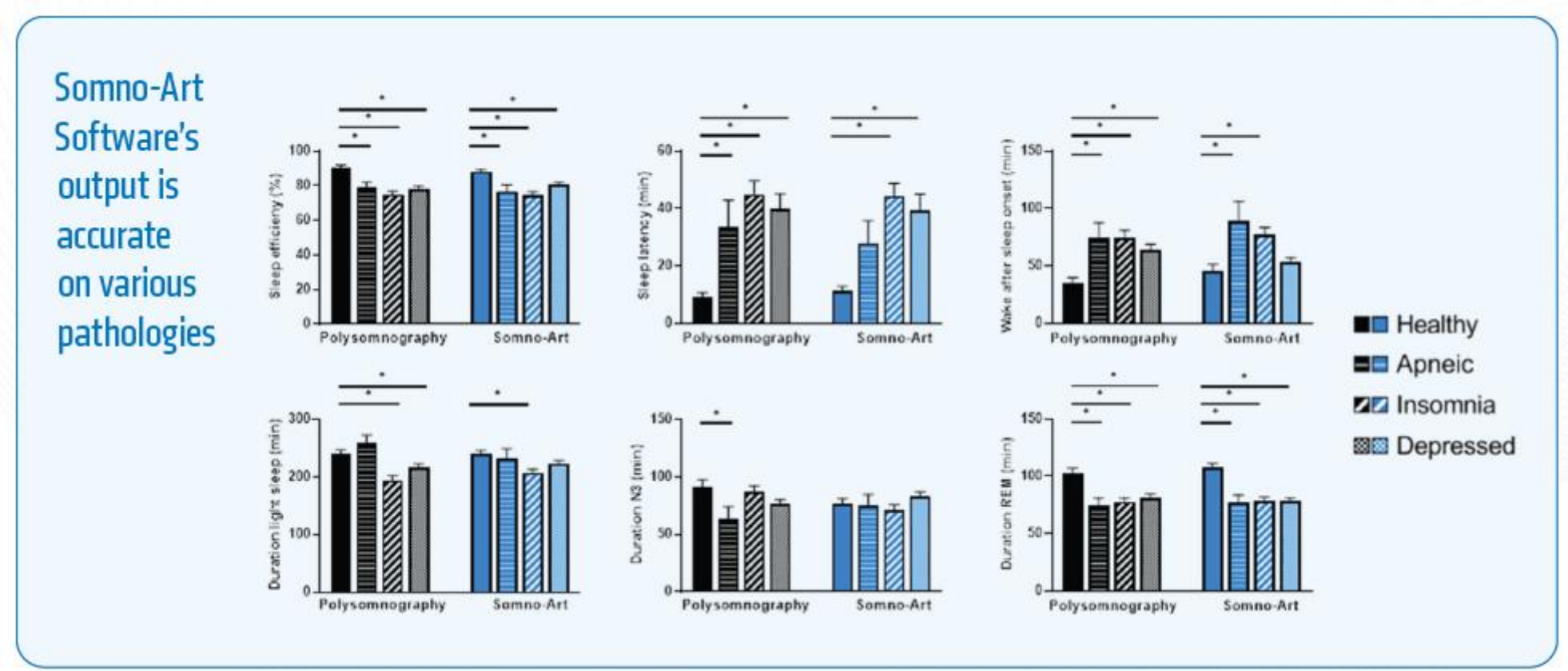
5. RESULTS TRANSMISSION

At the end of the study, all the reports and data are securely sent

Les membres AFSSI ont la parole



Les membres AFSSI ont la parole



Somno-Art: 5 points clés à retenir

- DM certifié CE
- Ambulatoire et simple d'utilisation pour le patient
- Analyse automatique des enregistrements
- Permet à tous les médecins d'accéder à des données robustes et validées cliniquement
- Designed and Made in France