# IXICO

Advanced Analytics. Intelligent Insights.

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# Delivering Insights in Neuroscience

"Advancing medicine and human health by transforming data into clinically meaningful insights."

IXICO is a premier neuroimaging provider helping biopharmaceutical companies maximize the value of their drug development pipelines by transforming data into clinically meaningful insights. Bringing together world-class therapeutic expertise, breakthrough analytics and operational excellence, IXICO is the proven partner of choice for imaging biomarker solutions in CNS clinical trials.

## Power of Neuroimaging

Neuroimaging, with its ability to visualize extraordinary information about the structural, functional and biochemical characteristics of the human brain, is a powerful tool in CNS clinical trials. In addition to providing key biomarker endpoints to measure therapeutic effects, it also allows drug development sponsors to gain critical efficiencies by optimizing trial sample size vis-à-vis statistical power.

For sponsors, however, it is challenging to translate the real value of neuroimaging into successful operationalization and trial outcomes due to complexities inherent in therapy-specific biomarker selection, patient recruitment strategies, choice of analysis methodologies and multi-center logistics.

With specialist neuroscience knowledge, AI-driven innovation and robust operational infrastructure, IXICO solutions are specifically designed to enable clients to address these challenges and realize the full power of imaging biomarkers in today's CNS trials.

## Supporting Entire Development Lifecycle

Our advanced neuroimaging solutions unlock clinically meaningful insights about drug safety and efficacy across the entire development lifecycle, from Phase I through to commercialization.

Supporting clients to make better informed decisions earlier in the development pathway, IXICO helps accelerate R&D decision making, de-risk clinical research and maximize the value of sponsors' drug development pipelines.

# Proven Therapeutic Know-how

Having focused solely on neurological disorders since our inception in 2004, IXICO teams are renowned specialist experts in CNS therapy areas. Blending specialist neuroscience domain knowledge, access to highly curated neurological patient data and proven pipeline algorithms to measure brain biomarkers, we help you directly answer your research questions including those related to disease symptoms, delivery mechanism, mode of action, drug safety and efficacy.

# End-to-End Services

**Study Design & Consultation:** Individually tailored consultation to define best imaging endpoints and analysis methodologies to deliver requisite insights

**Project Management:** Seamless start-up, management and delivery of your study overseen by a dedicated central point of contact to provide highest levels of client care and support

**Imaging Site Set-Up & Management:** Qualification, training and management including rigorous multi-center harmonization and standardization of image acquisition protocols

**Centralized Reading:** Image read by global network of renowned neuroradiologists and nuclear medicine physicians

**Image Analysis:** Meticulous, rigorous assessment by highly trained specialist analysts

**Regulatory Pathway:** Deployment of imaging biomarkers within regulatory compliant framework

**PET / SPECT Tracer Management:** Complete tracer supply management service

# CNS Therapeutic Areas

**Proven therapeutic expertise across major CNS indications including:**

- Alzheimer's Disease
- Huntington's Disease
- Multiple System Atrophy
- Parkinson's Disease
- Progressive Supranuclear Palsy
- Spinocerebellar Ataxia
- Friedreich's Ataxia
- Other Movement Disorders & Dementias

# Full Analysis Capabilities

**Radiology Eligibility and Safety Visual Reads**

**Volumetric MRI (vMRI)**
Optimized pipelines per therapeutic area and region

**Diffusion MRI (dMRI)**
ROI (LEAP ROI, JHU White Matter Labels)
Whole-brain Tractography / Connectivity

**Free Water Analysis**

**Resting State Functional MRI (rs-fMRI)**

**Task-based Functional MRI (tb-fMRI)**

**Arterial Spin Labeling (ASL)**

**Magnetic Resonance Spectroscopy (MRS)**

**Susceptibility Weighted Imaging (SWI)**

**Quantitative Susceptibility Mapping (QSM)**

**Molecular Imaging (PET and SPECT)**

**PET / SPECT Tracer Management**
• Complete tracer supply management service

**PET Visual Reads**

**Standardized Uptake Value Ratio (SUVR)**
• MRI-based and PET only analysis

**PET Centiloid Scales**

**Tracer Kinetics (Dynamic PET Binding Potential)**

**SPECT Visual Reads**

**SPECT Semi Quantitative Analysis**
• Striatal Binding Ratios – SBRs
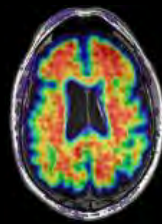
## Imaging Analysis

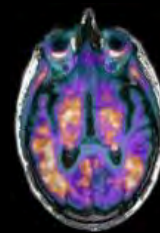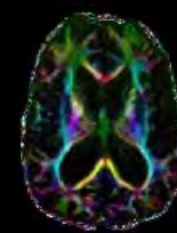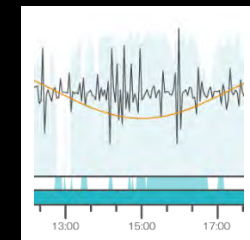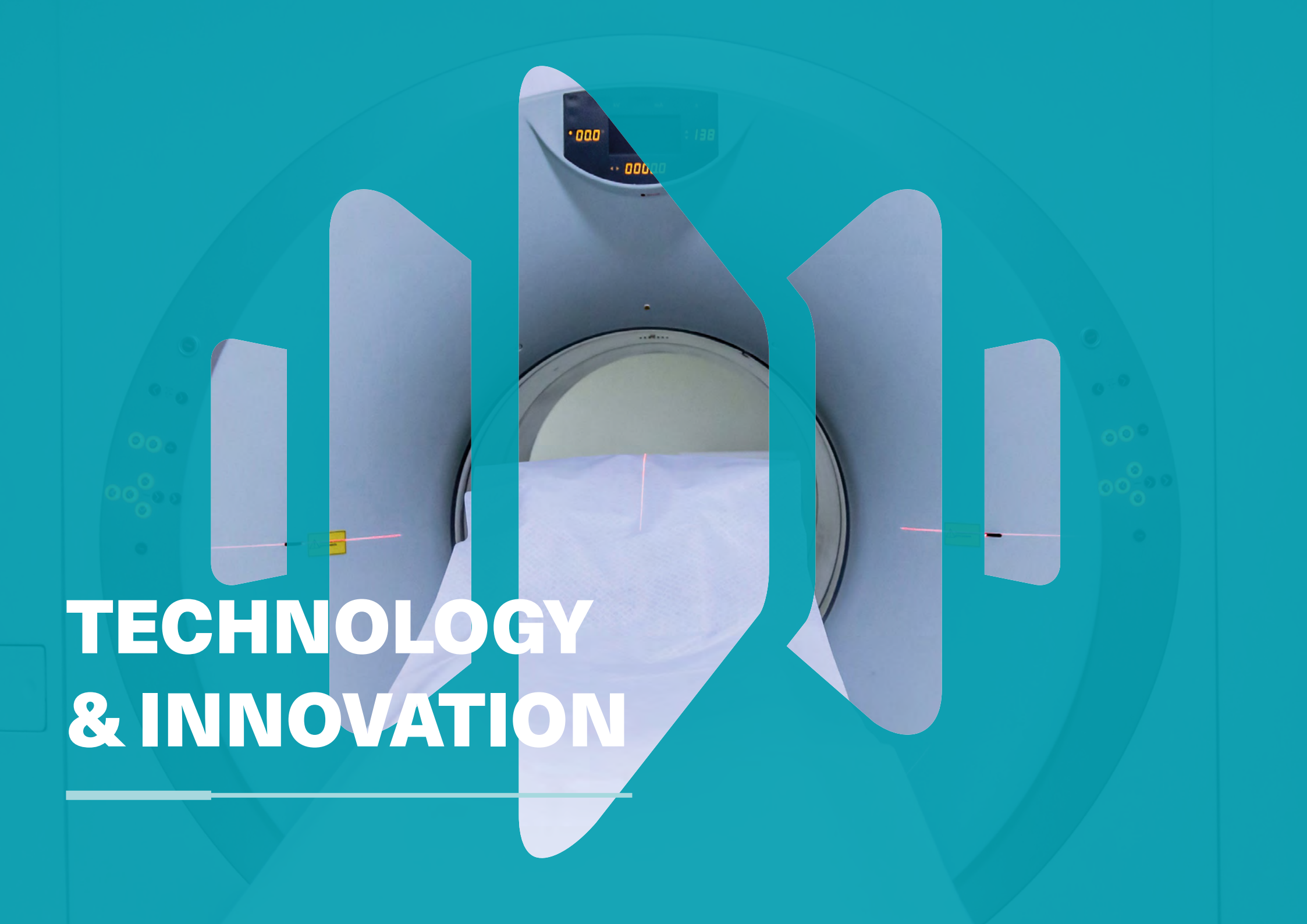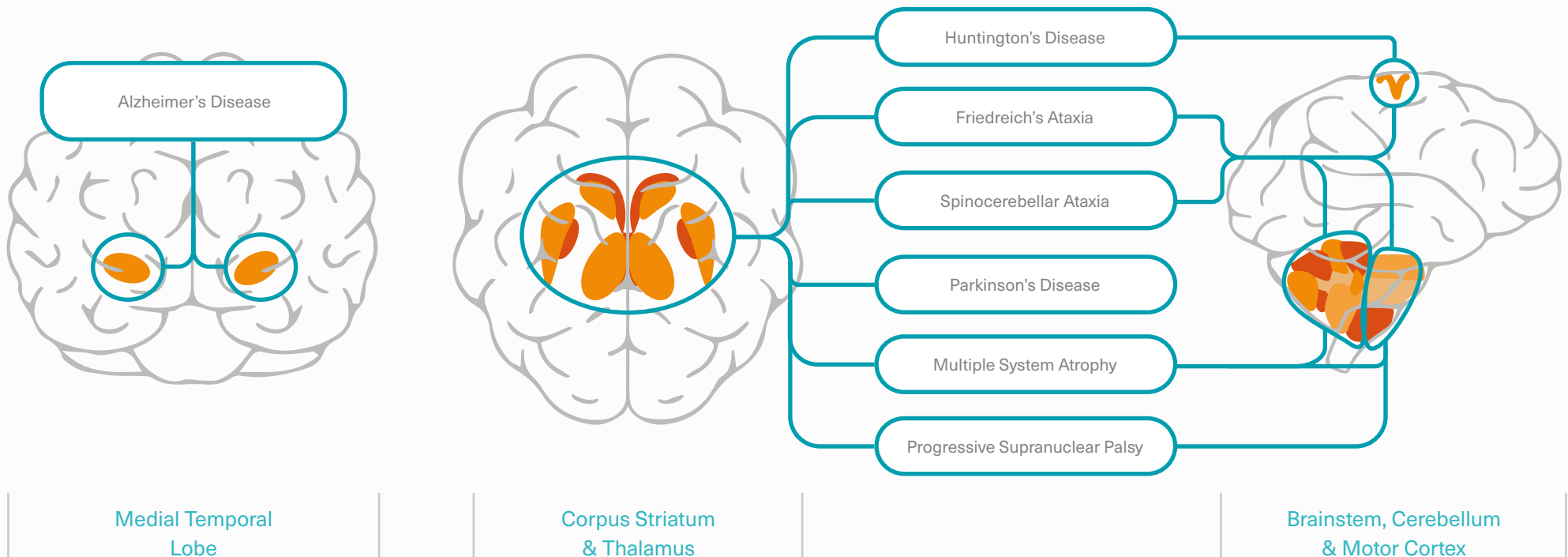| ELIGIBILITY / STRATIFICATION | SAFETY | EFFICACY | | | | |
|---|---|---|---|---|---|---|
| | | IMAGING | | | | BIOSENSOR |
| Structural MRI | PET / SPECT | Structural MRI | Structural MRI | PET / SPECT | Advanced MRI | Actigraphy |

# TECHNOLOGY & INNOVATION

# Cutting-edge Analytics

IXICO's therapeutic-area-specific validated AI algorithms provide world-class, ground-breaking analytics to enable accurate assessment of brain pathologies and disease-specific symptoms.

LEAP, the patented analysis technology with fully automated segmentation of over 150 brain structures, performs quantification of changes in both whole-brain and regional volumes.

Using multi-atlas propagation, a flexible and robust method for image segmentation, LEAP is optimized and validated for therapeutic area and region-specific segmentations.

## LEAP: AI Technology with Broad Therapeutic Application



Alzheimer's Disease

Huntington's Disease

Friedreich's Ataxia

Spinocerebellar Ataxia

Parkinson's Disease

Multiple System Atrophy

Progressive Supranuclear Palsy

Medial Temporal Lobe

Corpus Striatum & Thalamus

Brainstem, Cerebellum & Motor Cortex

# TrialTracker

TrialTracker, IXICO's proprietary image management platform, facilitates standardized capture, quality assurance, reading, analysis and reporting of clinical data across the entire image lifecycle.

Uniquely focused on simplifying workflows across different user types and processes, it seamlessly unifies the complex workflows between imaging centers, radiology / nuclear medicine readers, IXICO teams and sponsor personnel.

**Site**

**IXICO** Standardized capture, analysis and reporting of regulatory compliant clinical data

**Sponsor**

MR images

PET images

Clinical data

Biosensor data

**Upload**

**QC**

**Read**
Clinical interpretation: standardized expert reads

**Report**

**Pharma / Biotech Sponsor**

**Clinical Development**
Support the development of drugs in clinical trials

**Companion Product**
Support the use of drugs in the clinic: to match patients to treatment and to improve patient safety outcomes

Rich combination of longitudinal patient data driving product improvement

**Data**

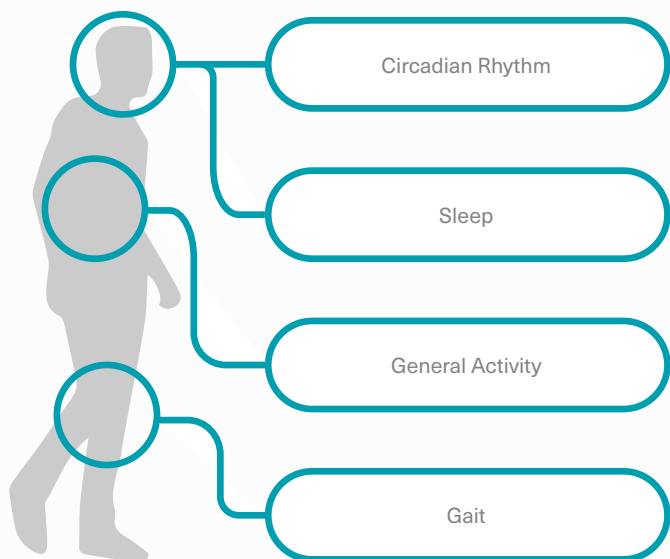Data driven, advanced machine learning based data analytics and disease models

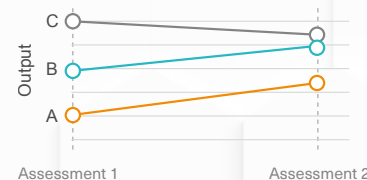**Analyze**

# Digital Biomarkers

Digital biomarkers offer valuable real-world data in clinical research.
As a pioneer in deploying emerging wearable technologies
in clinical research settings, IXICO is at the forefront of developing
and validating machine-learning tools to analyze biosensor data
including actigraphy outputs.

## Digital Outcome Measures in Drug/Therapeutics Development

IXICO product utility

- Circadian Rhythm
- Sleep
- General Activity
- Gait

**Daily profile**

C
B
Output
A

Assessment 1          Assessment 2

**Monitoring disease progression**

- Risk
- Diagnosis
- Prognosis

**Cohort selection & stratification**

- Safety
- Side effects
- Treatment response

**Drug effects**

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