



Clinical Development Plan  
June 2023

# You Play, We Care.

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PRIX GALIEN USA<sup>1</sup>

Clinical development plan

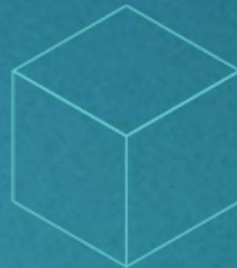
## Clinical data for OdySight comes from a variety of sources



**TILAK CLINICAL  
TRIALS**



**INVESTIGATOR  
INITIATED STUDIES**



**REAL-WORLD  
ANALYSIS**




**PATIENT CLINICAL  
CASES**



## Clinical development plan

## Our path to broaden the usage of OdySight

	Goals	Status
	<b>TIL-001</b> OdySight clinical tests are equivalent to in-clinic tests, <b>when supervised within the clinic</b>	Completed
	<b>TIL-002</b> OdySight clinical tests are equivalent to in-clinic tests, <b>without supervision at home</b>	Completed <i>(waiting for publication)</i>
	<b>TIL-003</b> OdySight has <b>positive impact</b> on the <b>management of patients</b>	Ongoing study
	<b>BPI Study</b> OdySight-based monitoring strategy in macular edema can <b>reduce HCRU and improve overall patient care</b>	Protocol initiated



## Clinical development plan

# TIL-001 : evaluate the medical modules on OdySight under supervision

## OBJECTIVES

- Evaluate the medical modules in clinic and compare them to the gold standard tests for **visual acuity**, **contrast sensitivity** and **Amsler Grid**

## STUDY PERIMETER



120 Eyes



1 Clinical center

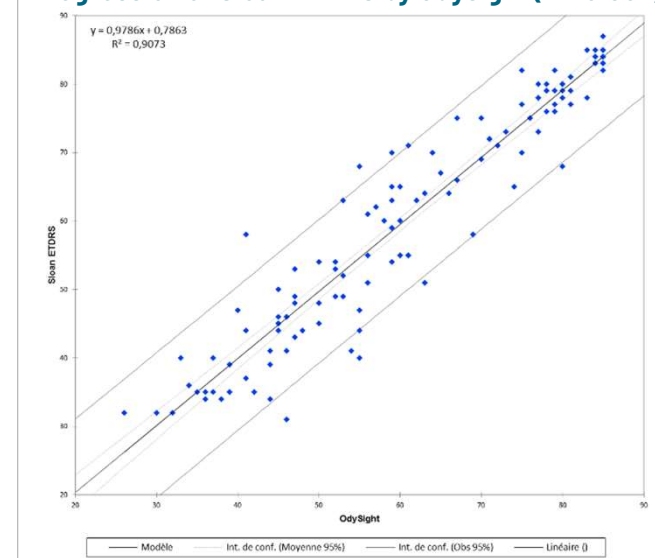
## RESULTS

- **Visual acuity:** A Bland-Altman analysis demonstrated that there was no disagreement between the results of the OdySight and the gold standard
- **Contrast sensitivity:** A Bland-Altman analysis showed a broader disagreement
- **Amsler grid:** A McNemar test showed no significant difference

## CONCLUSIONS AND LEARNINGS

- **OdySight could be used for remote monitoring of visual acuity** between clinic visits and potentially assist in follow-up planning

Regression of Sloan ETDRS by OdySight ( $R^2=0.907$ )



## Clinical development plan

# TIL-002 : evaluate the medical modules on OdySight in real-life

Caveat: final publication is not yet available

## OBJECTIVES

- Assess the equivalence between the visual acuity module of **OdySight at home** and standardized methods performed in clinic
- Assess relations between the ETDRS visual acuity at a 4-meter distance and near visual acuity evaluated with OdySight at home

## STUDY PERIMETER



105 Eyes



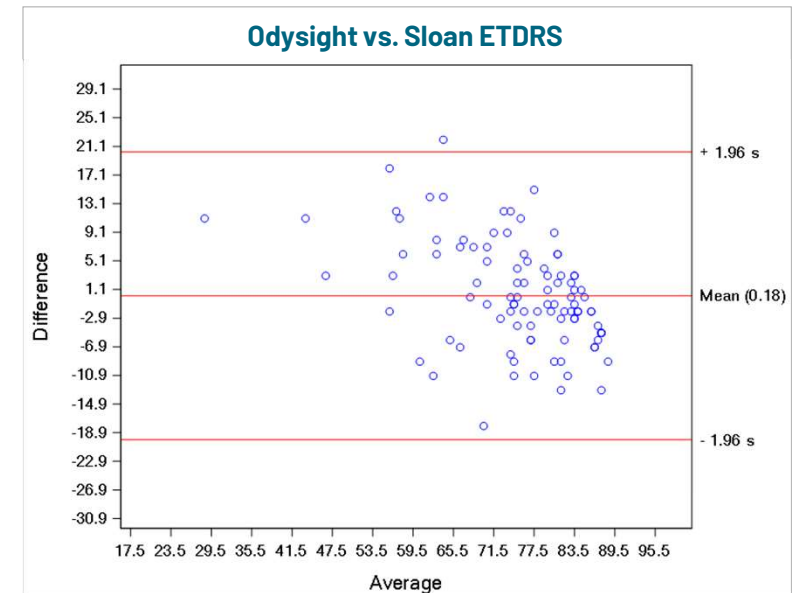
3 Clinical centers

## RESULTS

- Equivalence between OdySight and standard methods has been demonstrated**
- A high variability has been observed, but this variability is comparable to those between existing standard methods

## CONCLUSIONS AND LEARNINGS

- OdySight could be used for remote monitoring of visual acuity** between clinic visits and potentially assist in follow-up planning



## Clinical development plan

# TIL-003 : evaluate the impact of OdySight in patient management in real-life

### OBJECTIVES

- Assess the impact of OdySight in the management of patients suffering from impaired visual acuity by comparing notifications triggered by OdySight and clinical data extracted from medical records in patients using OdySight
- Assess the sensitivity, specificity, Positive and Negative Predictive Value

### STUDY PERIMETER



>400 Eyes



9 Clinical centers

### RESULTS EXPECTED BY END OF 2023



Additionally, a study is ongoing with the Texas Tech University Health Center to evaluate the consistency between various apps visual acuity measure and in the clinic (ran by Dr Jay Samanta)



## Clinical development plan

# Alerts system real-world analysis by Aix Vision

## OBJECTIVES

- Analyze the implementation and clinical efficacy of OdySight for the **remote monitoring of patients with maculopathy**

## STUDY PERIMETER



22 Patients



483 Tests



1 Year

## RESULTS

- 61%** of patients **completing at least one test**
- 24% retention rate** at 9 months
- 19 alerts** processed by the clinical team (*of which 6 resulting in an injection*)

## CONCLUSIONS AND LEARNINGS

- 32% of alerts led to a change in the treatment of the patient**
- «Both the occurrence of an alert and the « player » profile are strong predictors of retention»
- OdySight provides patients and practitioners an **added level of protection**



## Clinical development plan

# At-home screening for exudative recurrence of macular diseases

### OBJECTIVES

- Describe the value of the Odysight in addition to a classical follow-up regimen in the **detection of exudative recurrences in patients with macular disease**

### STUDY PERIMETER

 **123<sup>1</sup>** Patients  **3** Clinical centers  **2** Years

### RESULTS

- 77% retention rate** at day 90
- 36% retention rate** at day 270
- 39 alerts** on 18 patients, of which:
  - **8** resulted to an **injection**
  - **12** were **true positive**
  - **27** were deemed **false positive**

### CONCLUSIONS AND LEARNINGS

- 20% of alerts led to a change in treatment paradigm**
- OdySight has demonstrated a **similar efficacy** compared to **app based on hyperacuity technology**

#### Note:

- In this study OdySight performance was assessed based on the ability to detect a recurrence of edema, which is not OdySight's claim (rather able to detect a decrease in Visual Acuity)
- Retention rates mentioned in the study include patients that never installed the app, as such rates have been recalculated

1. Of which 47 using the app  
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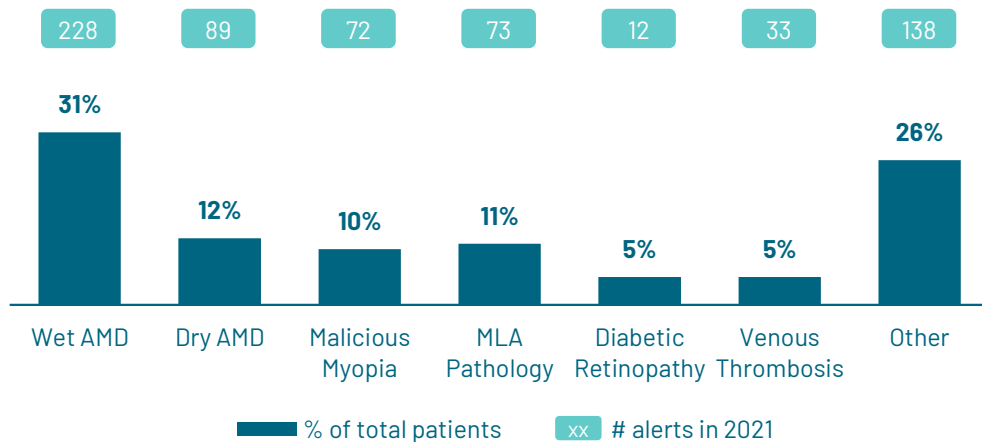




## Clinical development plan

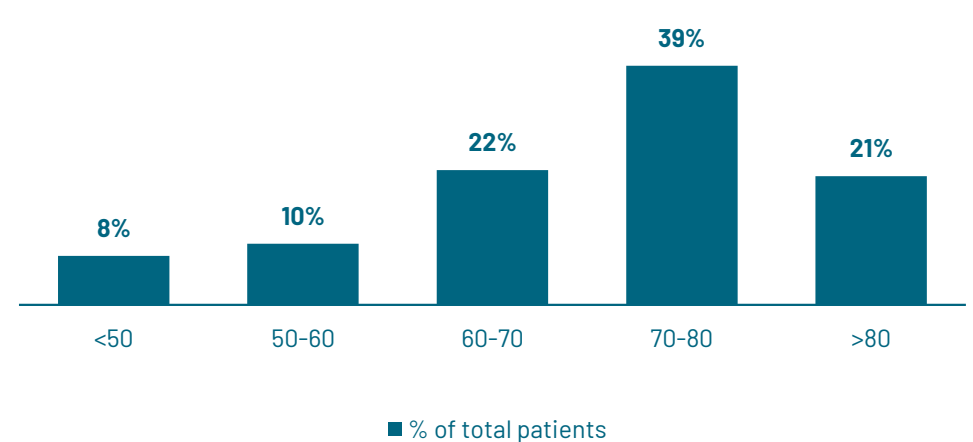
# Overview of OdySight users through real world data (analysis of 2021)

### Breakdown of eye pathology among OdySight users



- OdySight was developed to address the growing need for remote monitoring of visual function among **patients suffering from AMD and other chronic eye diseases**
- OdySight has been **most recommended** for patients diagnosed of **wet AMD**

### Age cohorts among OdySight users



- **Most frequent users** are the **age cohort of 70-80** years as the targeted pathology affect often the elders
- **The number of patients decreases greatly with the age of the cohort**

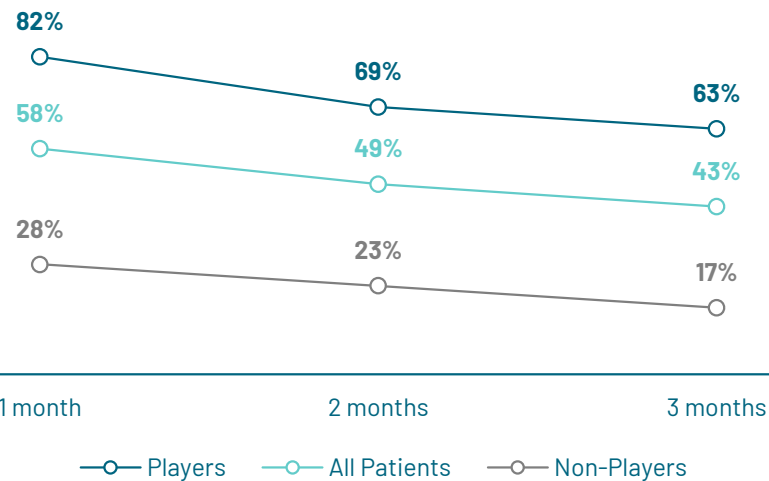


1. Players with less than 3 sessions (in eye tests or puzzles) or with a number of puzzles completed less than 10% of their total number of sessions

## Clinical development plan

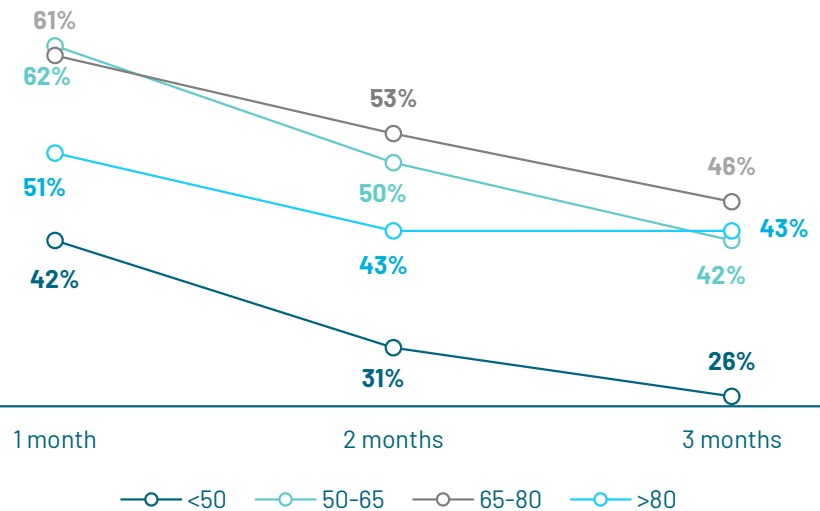
# Gaming greatly improves the average retention rate (analysis of 2020)

Average retention rate per type of OdySight users



- OdySight has an average **retention rate of 43% at 3 months**
- Players have a much better retention rate than non-players ones

Average retention rate per age cohorts








- Patients at age >80 have **43% retention rate at 3 months** (same than at 2 months)
- For the group 50-80+, **retention rates converge towards 43%**
- Retention rate is the **lowest among the users below 50 years**



## Clinical development plan

# OdySight has proven its efficiency through many clinical cases

		Project Data			Examples of clinical cases
		Start date	% Patients who downloaded OdySight	# of alerts	
	Institute of Sourdille-Atlantique	Oct-19	<b>77%</b> (06/2020)	<b>15</b> (06/2020)	After 2 alerts, a patient scheduled an early meeting, leading to an injection (2 months before the due date)
	Clinical center Rabelais	Oct-19	<b>79%</b> (05/2020)	<b>17</b> (05/2020)	A patient called the clinical center following an alert sent by OdySight leading to an urgent meeting and an injection (1 month before the due date)
	Clinical center des Arceaux	Nov-19	<b>90%</b> (04/2020)	<b>25</b> (04/2020)	A complication was noticed by OdySight leading to an injection (2 weeks before the due date)
	Hospital des XV-XX	Oct-18	<b>72%</b> (07/2020)	<b>41</b> (07/2020)	After 1 month of decrease in visual acuity, the patient is summoned to the clinical center, resulting in an injection (5 weeks before the due date)
	Center Visis	Nov-19	<b>70%</b> (02/2020)	n.a.	An alert was sent by OdySight resulting in an urgent meeting with the doctor and an injection (1 month before the due date)



# All publications

TIL-001: <https://link.springer.com/article/10.1007/s40123-019-0203-9>

Clinical cases: [Retrouvez les dernières actualités d'OdySight](#)

Investigator initiated study 1: <https://pubmed.ncbi.nlm.nih.gov/34024655/>

Investigator initiated study 2: <https://pubmed.ncbi.nlm.nih.gov/36078941/>

Real-world data analysis (published by Tilak): [OdySight: Real-World Data Analysis of a Mobile Medical Application for Ophthalmology \(ophthalmoscience.com\)](#)

