# Validation of Suprachoroidal Injection Training Program with a Synthetic Eye Model

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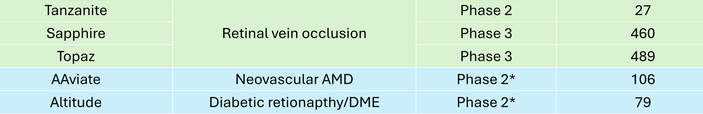
PHOTOGRAPHY ALLOWED

## PURPOSE

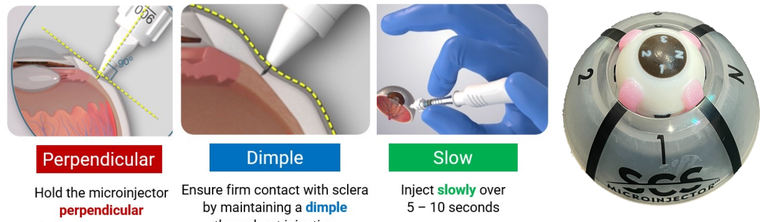
To demonstrate the effectiveness of a proprietary training program for suprachoroidal injection with the SCS Microinjector®, the device constituent of an FDA approved combination product, XIPERE®

*Figure 1: SCS Microinjector Syringe with 900 µm Microneedle*




The suprachoroidal injection training program with the SCS Microinjector® is THE ONLY **CLINICALLY VALIDATED** training program and over 15,000 injections have been completed to date.

*Figure 2: Proprietary training program: a custom training eye model with training material content (Included in figure is an excerpt of the critical tasks associated with the injection procedure)*




## BACKGROUND

- Over 15,000 suprachoroidal injections have been performed with the SCS Microinjector, in over 15 clinical trials (Table 1) and commercial use. It is the only drug delivery device constituent approved for suprachoroidal injection in a combination product by the FDA.
- As a new route of administration, a robust and standardized training procedure was developed to ensure consistency across multiple clinical trials, indications, products, and countries.
- A two-tiered proprietary training program was developed: Training the Trainers (TtT) and physician training (PT).
  - To date, there are 62 global certified trainers and thousands of trained retinal specialists.
- Training material, including a custom-developed model eye and training content (Figure 2), has been developed to provide an effective training experience.

A new Category 1 CPT Code has contributed to expanded commercial use and adoption of suprachoroidal injections with the SCS Microinjector® with XIPERE® (Bausch + Lomb).

*Table 1: Clinical trials utilizing the SCS Microinjector (* indicates ongoing trial)*

| Study Name | Indication | Phase | # of Injs (est.) | # of Subjects (est) |
|---|---|---|---|---|
| OASIS | Neovascular AMD | Phase 1/2a | 26 | 27 |
| ODYSSEY | | Phase 2 | 84 | 40 |
| Dogwood | Uveitic macular edema Uveitis | Phase 2 | 22 | 22 |
| Azalea | | Phase 3 | 70 | 38 |
| Peachtree | | Phase 3 | 192 | 96 |
| UME Study | | Phase 3 | Not Public | Not Public |
| DME Study | | Phase 2 | | |
| Tybee | Diabetic macular edema (DME) | Phase 2 | 72 | 36 |
| Hulk | | Phase 1/2a | 39 | 20 |
| Tanzanite | Retinal vein occlusion | Phase 2 | 27 | 27 |
| Sapphire | | Phase 3 | 460 | 230 |
| Topaz | | Phase 3 | 489 | 163 |
| AAviate | Neovascular AMD | Phase 2* | 106 | 106 |
| Altitude | Diabetic retionapthy/DME | Phase 2* | 79 | 79 |
| AU011 P2 | Choroidal melanoma | Phase 2 | 168 | 20 |
| CoMpass Trial | | Phase 3* | 126 | 7 |

Clearside has refined the training process for suprachoroidal delivery using the SCS Microinjector® over the course of numerous clinical stage programs around the world.

## METHODS

- Three (3) surveys have been completed to evaluate user understanding of the procedure after training.
  - Early Adopter Feedback: twelve (12) retinal/uveitis specialists with 10+ suprachoroidal injections of XIPERE completed a 37-question survey.[1]
  - A total of 33 people were trained and surveyed to evaluate the adequacy of the training program.[2]
  - User survey for injecting physicians and observers from one of the Clearside Phase 3 studies for uveitis.[3]
- Critical tasks related to the procedure were determined with a User-Related Risk Analysis (URRA).[4]
- Effectiveness of the training was confirmed with device and procedural complaint data during multiple clinical trials with a total of 444 injections.
- Training model effectiveness impact was ranked from level 1 to 5, from trainee satisfaction to impact of procedure at a systemic health care level (Table 2). [5,6]

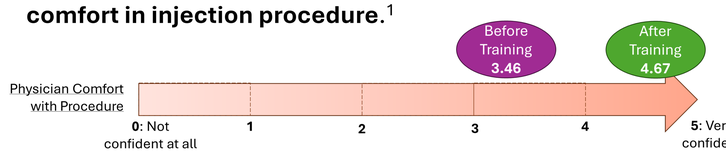
*Table 2: Translational outcome of simulation-based learning*

| Levels | Parameter | Definition | Example |
|---|---|---|---|
| Level 1 | Internal acceptability | The trainee's satisfaction with using the simulator | Favorable responses from feedback forms or post-training survey questionnaires |
| Level 2 | Contained effects | Changes in performance in the simulation context | Changes in performance in the simulation context |
| Level 3 | Downstream effects | Behavioral change in the clinical context | Transfer of knowledge/skills to clinical practice |
| Level 4 | Target effects | Direct changes to patient outcomes | Reduce rates of complications |
| Level 5 | Collateral effects | Changes on a wider, systemic levels | Cost saving; skill retention |

**Disclosure**: All authors (CW, NF and RA) are employees of Clearside Biomedical, Inc.

## RESULTS

- Early adopter survey showed **training improved physician comfort in injection procedure**.[1]




- Over 64% of trainees believe **no mandated retraining was necessary**, with the rest recommending annual re-training or refresher.[2]
- Clinical trial questionnaire showed **84% of physicians did not consider suprachoroidal injection presenting new challenges, compared to other injections**.[3]
- **No device / administration related complaints** were received across 4 recent clinical trials with three different drug products where current training program was implemented.[7]

Suprachoroidal injections are different from other ocular injection procedures, but specialized training improves physician confidence.

## CONCLUSIONS & DISCUSSIONS

- Based on the criteria in Table 2 and the effectiveness assessment of the training (low complaint rates, increased physician comfort with procedure, and positive efficacy outcomes), this training program is rated at Level 4 for reducing possible rates of procedural complications, translating to **direct clinical benefits.**
- This **validated program is effective** in informing physicians of the critical tasks associated with suprachoroidal injections with the SCS Microinjector.

Clearside's proprietary training program, inclusive of the custom eye model and the training material content, has benefited from its wide use in investigational and commercial settings.

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