Patient Retention Strategies for Long-Term Extension Aesthetic Studies: Collagenase Clostridium Histolyticum-aaes (QWO™) Clinical Study Experience

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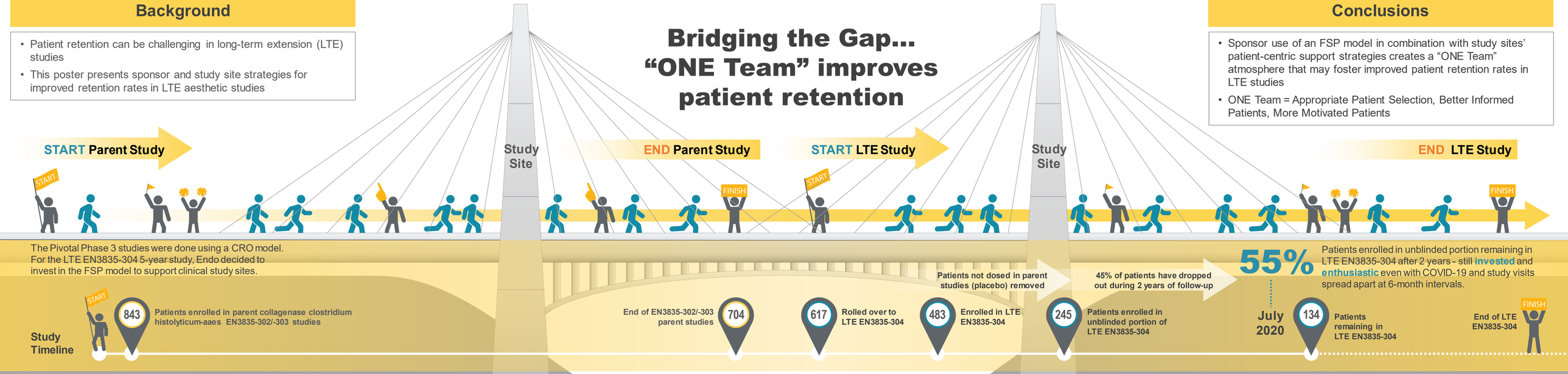
Background

- Patient retention can be challenging in long-term extension (LTE) studies
- This poster presents sponsor and study site strategies for improved retention rates in LTE aesthetic studies

Bridging the Gap… "ONE Team" improves patient retention



The Pivotal Phase 3 studies were done using a CRO model. For the LTE EN3835-304 5-year study, Endo decided to invest in the FSP model to support clinical study sites.

Study Timeline

- START
- 843 — Patients enrolled in parent collagenase clostridium histolyticum-aaes EN3835-302/-303 studies
- End of EN3835-302/-303 parent studies — 704
- 617 — Rolled over to LTE EN3835-304
- Patients not dosed in parent studies (placebo) removed
- 483 — Enrolled in LTE EN3835-304
- 45% of patients have dropped out during 2 years of follow-up
- 245 — Patients enrolled in unblinded portion of LTE EN3835-304
- July 2020
- 55% — Patients enrolled in unblinded portion remaining in LTE EN3835-304 after 2 years - still **invested** and **enthusiastic** even with COVID-19 and study visits spread apart at 6-month intervals.
- 134 — Patients remaining in LTE EN3835-304
- End of LTE EN3835-304
- FINISH

Conclusions

- Sponsor use of an FSP model in combination with study sites' patient-centric support strategies creates a "ONE Team" atmosphere that may foster improved patient retention rates in LTE studies
- ONE Team = Appropriate Patient Selection, Better Informed Patients, More Motivated Patients

Sponsor-Study Site FSP Model

Contract Research Organization (CRO) Model

Study operations fully outsourced

Sponsor — Limited or no sponsor-study site contact — Site

Inconsistencies, decreased quality control, and less flexibility/scalability

VS

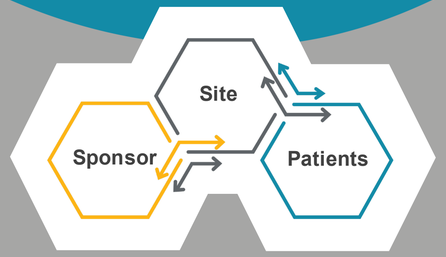
Functional Service Provider (FSP) Model

Clinical Operations personnel are engaged in study management/oversight

Sponsor, Site, Patient

Consistency and expertise, increased quality control, active involvement, rapid/flexible problem resolution, and greater flexibility/scalability

Sponsor FSP Model



Sponsor FSP Model

Study Site-Patient Relationship

- Sites supported by the sponsor share the excitement and responsibility of the study outcome. This is accomplished by building a relationship between patient and site using:
  - Dedicated support staff for patient contact
  - Customized and consistent personal contact
  - Flexible scheduling
  - Visit reminders
  - Personal notes
  - Birthday/holiday cards

Patients — Site Staff

The QWO™ Experience

Collagenase clostridium histolyticum-aaes (**QWO**) was approved by the Food and Drug Administration in July 2020 as injectable treatment for moderate-to-severe cellulite in the buttocks of adult women. This case study highlights patient retention outcomes in the ongoing QWO LTE EN3835-304 study that is associated with identical pivotal studies EN3835-302 and -303.

ASDS (AMERICAN SOCIETY FOR DERMATOLOGIC SURGERY) • OCTOBER 9–11, 2020 (VIRTUAL)

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INDICATION AND IMPORTANT SAFETY INFORMATION FOR QWO™ (collagenase clostridium histolyticum-aaes)

INDICATION

QWO is indicated for the treatment of moderate to severe cellulite in the buttocks of adult women.

IMPORTANT SAFETY INFORMATION FOR QWO

CONTRAINDICATIONS

QWO is contraindicated in patients with a history of hypersensitivity to collagenase or to any of the excipients or the presence of infection at the injection sites.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions including anaphylaxis have been reported with the use of collagenase clostridium histolyticum. If such a reaction occurs, further injection of QWO should be discontinued and appropriate medical therapy immediately instituted. Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions.

Injection Site Bruising

In clinical trials, 84% of subjects treated with QWO experienced injection site bruising. Subjects with coagulation disorders or using anticoagulant or antiplatelet medications (except those taking ≤150 mg aspirin daily) were excluded from participating in Trials 1 and 2.

QWO should be used with caution in patients with bleeding abnormalities or who are currently being treated with antiplatelet (except those taking ≤150 mg aspirin daily) or anticoagulant therapy.

Substitution of Collagenase Products

QWO must not be substituted with other injectable collagenase products. QWO is not intended for the treatment of Peyronie's Disease or Dupuytren's Contracture.

ADVERSE REACTIONS

In clinical trials, the most commonly reported adverse reactions in patients treated with QWO incidence ≥ 10% were at the injection site: bruising, pain, nodule and pruritus.

Please see accompanying Full Prescribing Information for QWO.

endo aesthetics

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