# Renishaw Drug Delivery System (RDDS)

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Renishaw Neuro Solutions
18 November 2020

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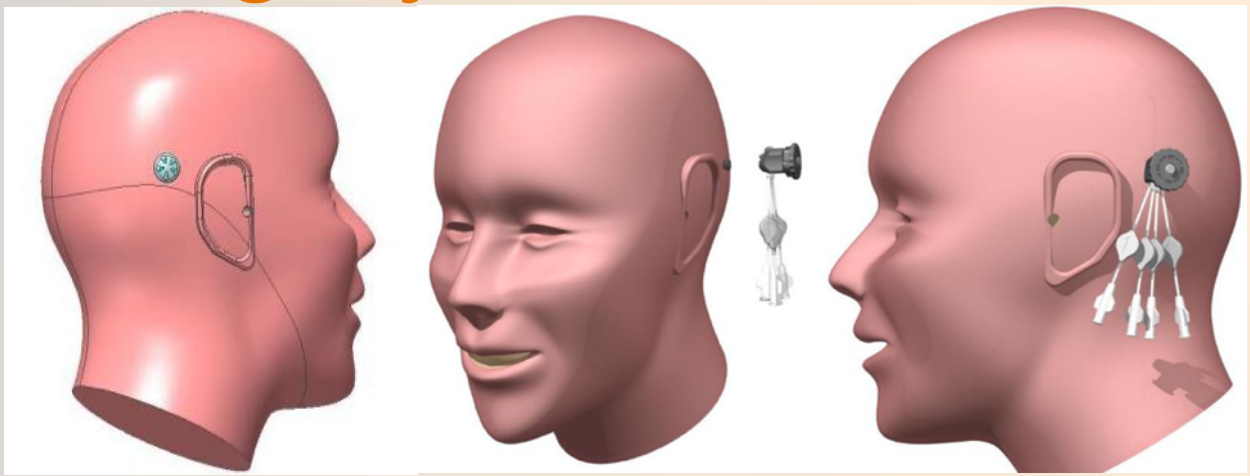
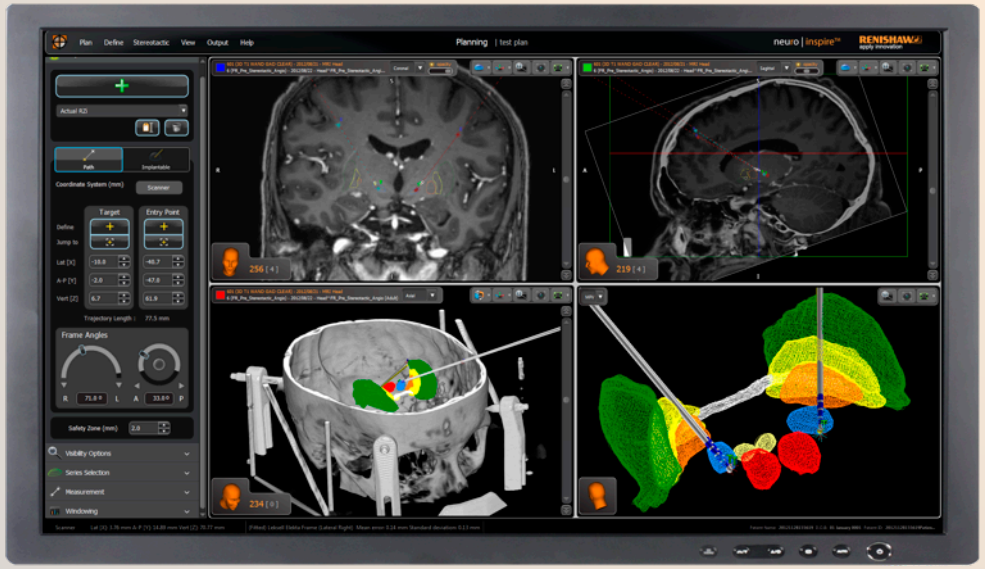
# Surgery and infusions









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# Content

- Primary Endpoints
- 
- Secondary Endpoints
- Exploratory Endpoint
- Learning from trial and future steps


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# Objectives of Drug Delivery Device

Primary objectives of this study were;

- **The safety** of the drug delivery system
- **The accuracy** of the drug delivery system

Secondary objectives of this study were;

- **Port stability**
- **Patency** (did it remain ‘open’, lack of obstruction)

Exploratory objective was

- **Examination of the infusion within the brain**



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# Primary endpoint - Safety

- Adverse Device Events (ADE)

An Adverse Device Event (ADE) is an Adverse Event related to the drug delivery device

- Serious Adverse Device Events (SADE)

A Serious Adverse Device Event (SADE) is a Serious Adverse Event related to the drug delivery device



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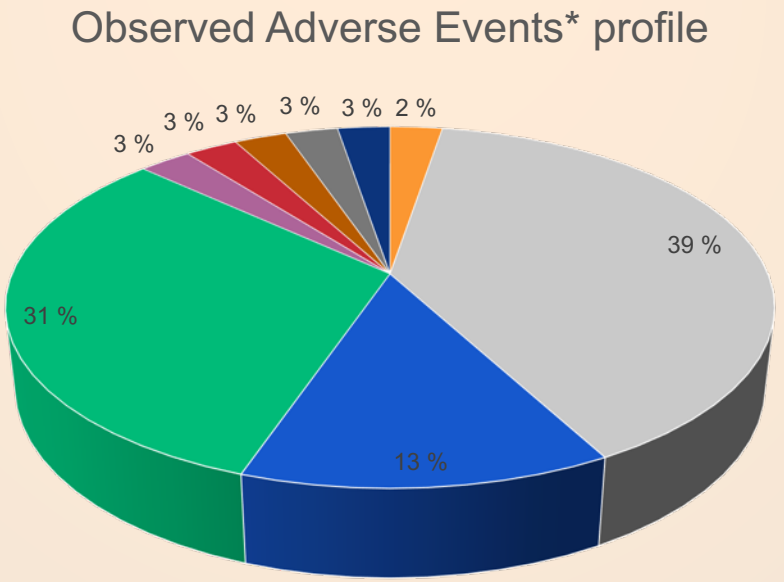
# Primary endpoint - Safety




* All ADEs before first treatment dosing



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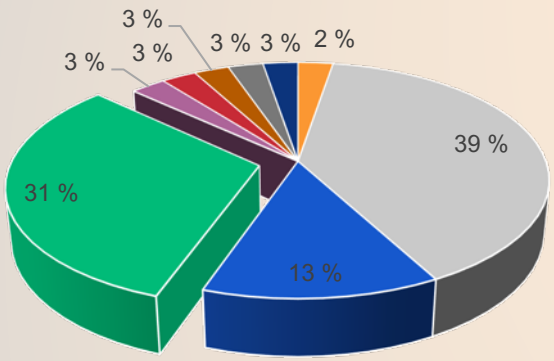
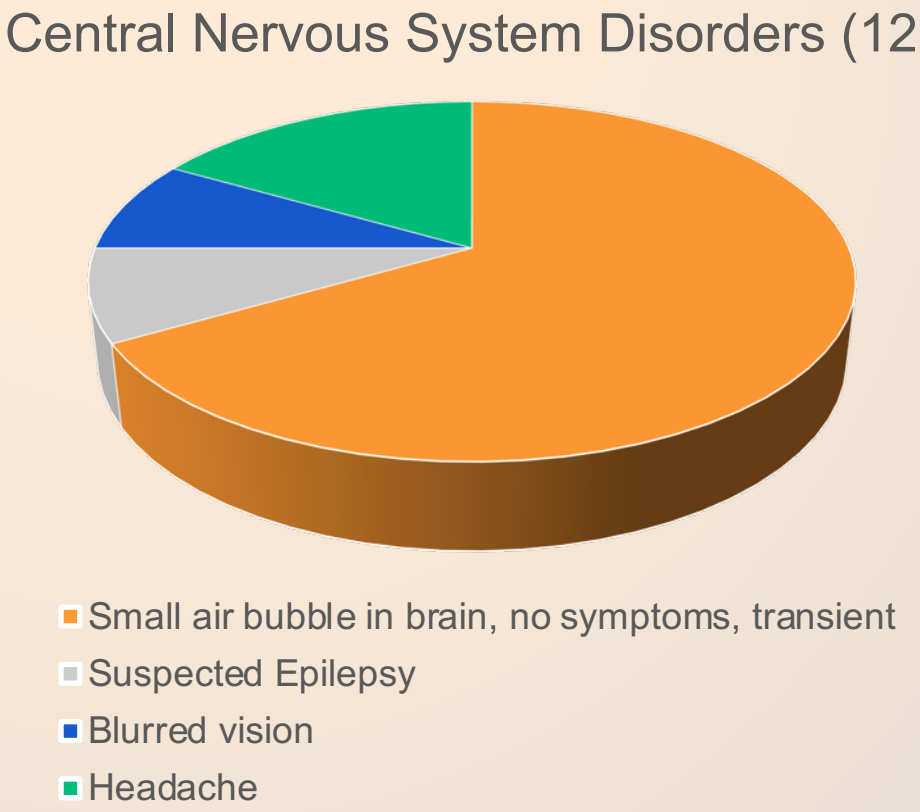
# Primary endpoint - Safety



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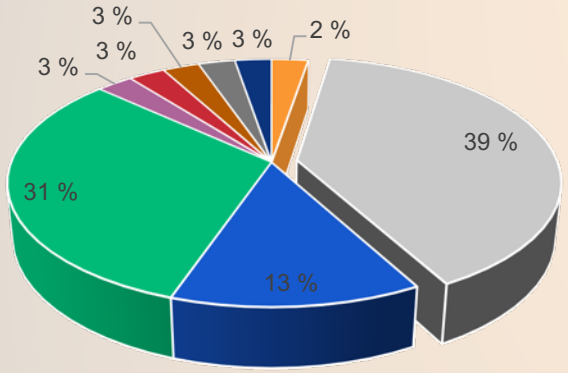
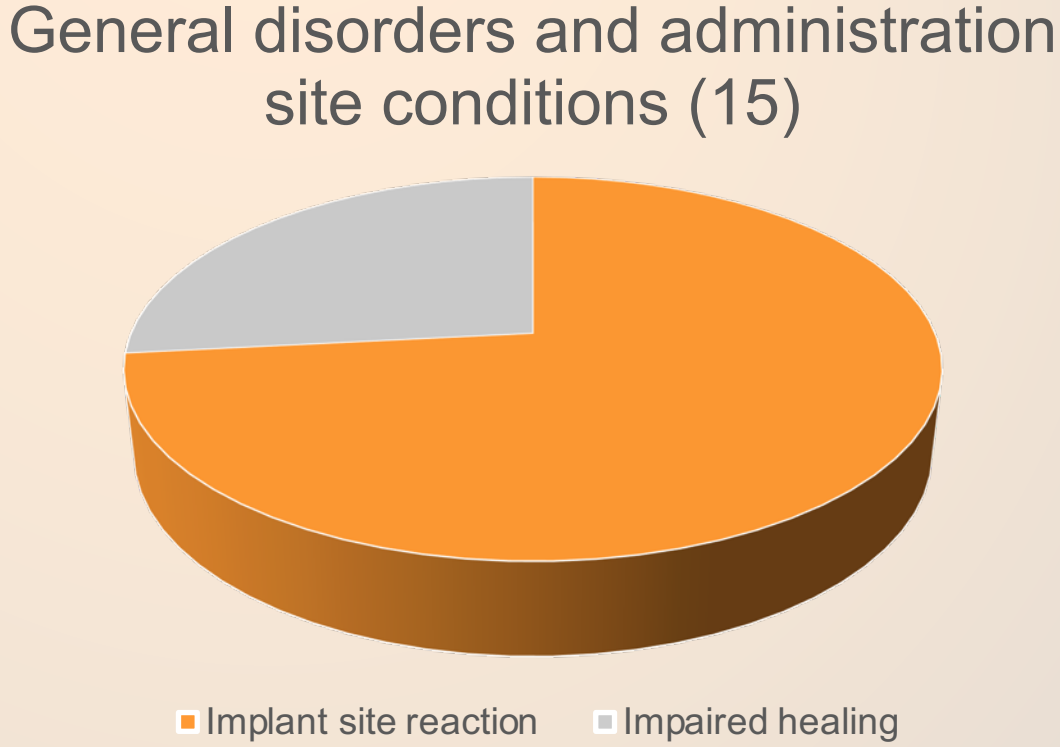
# Primary endpoint - Safety



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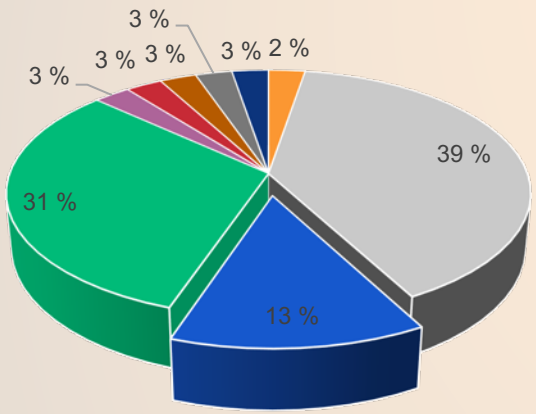
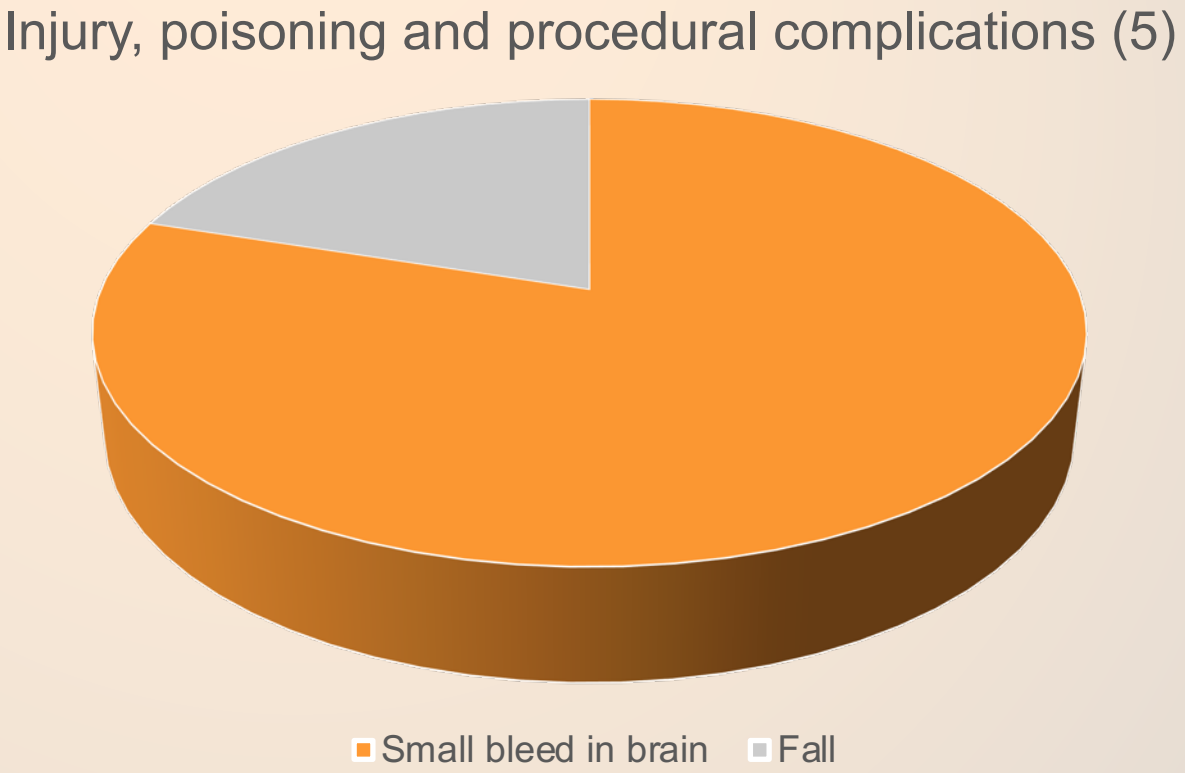
# Primary endpoint - Safety



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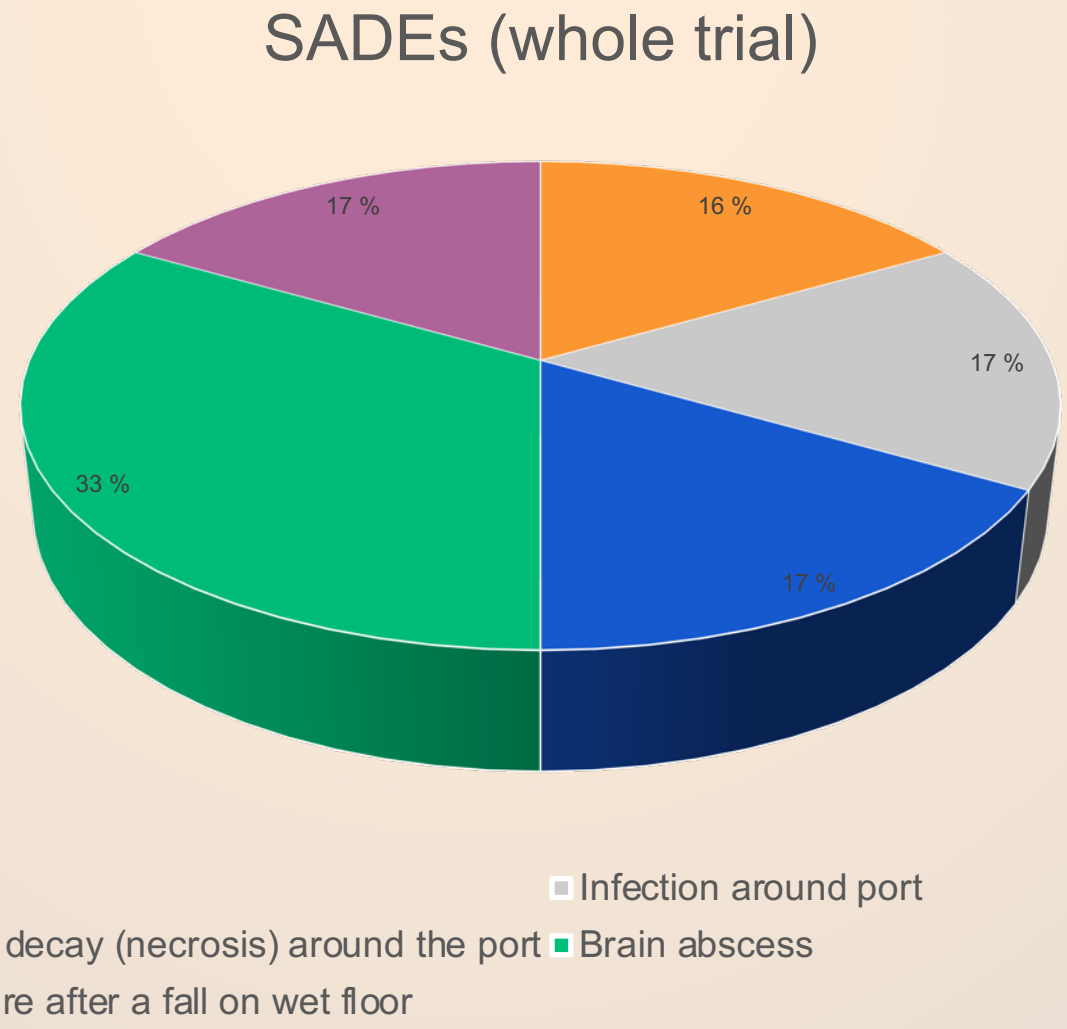
# Primary endpoint - Safety



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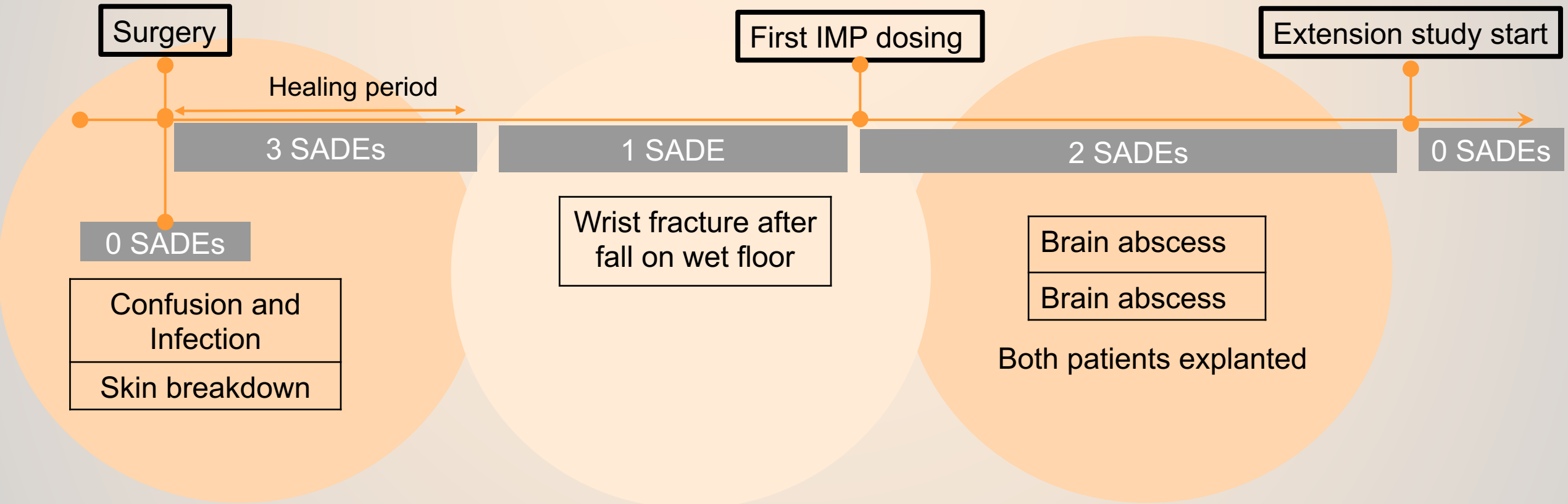
# Primary Endpoint - Safety




All SADEs recovered



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# Primary endpoint - Accuracy

## Anatomical accuracy

100% catheters in Putamen

## Positional accuracy

64 out of 68 catheter tips within 3mm of planned target (94.1%)

| | |
|---|---|
| Average | 1.5 mm |



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# Secondary Endpoints

**Patency** (openness, lack of obstruction)

99.8% of catheters remained patent throughout the trial

**The stability of the transcutaneous port**

100% of ports were stable throughout the trial



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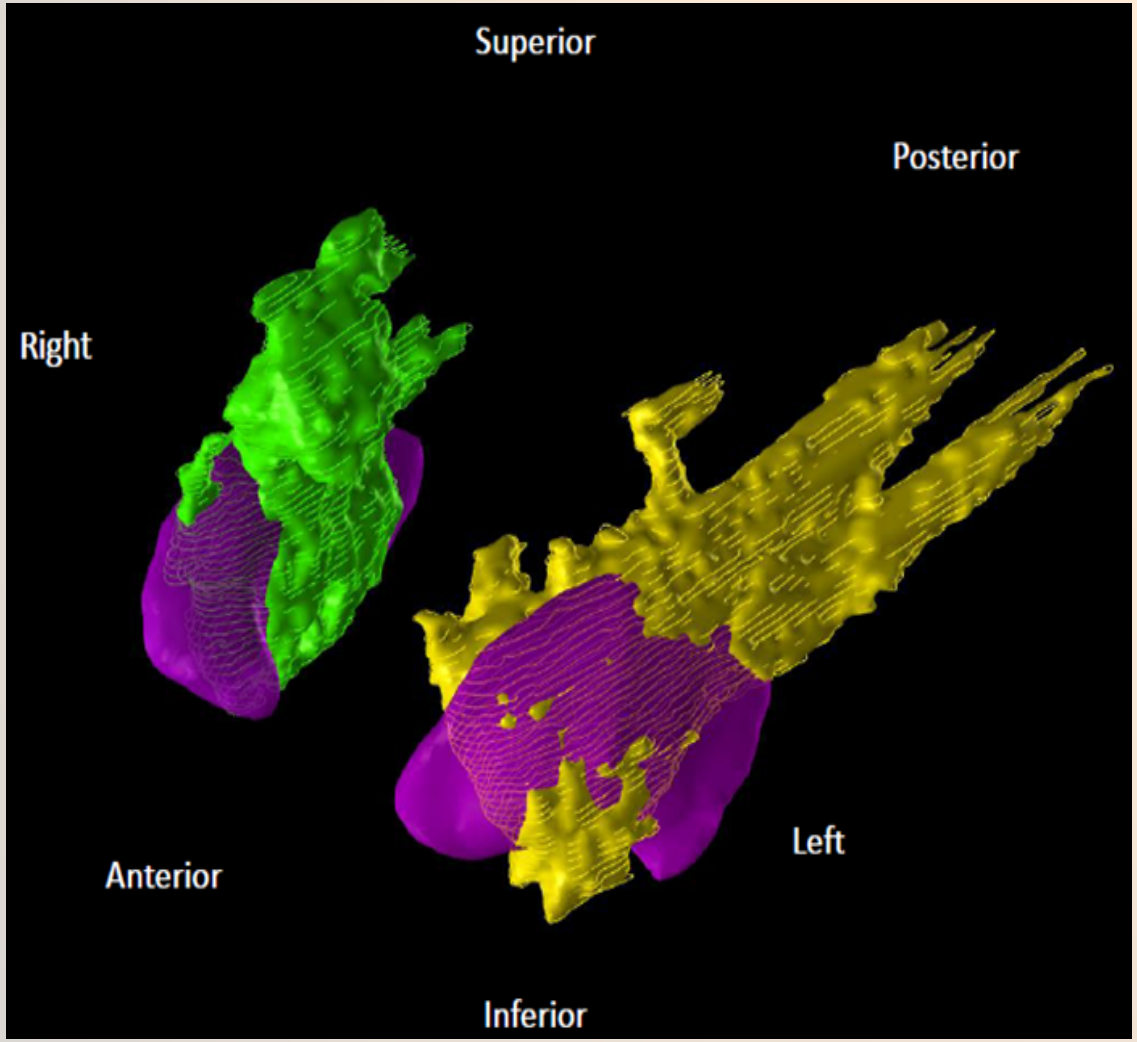
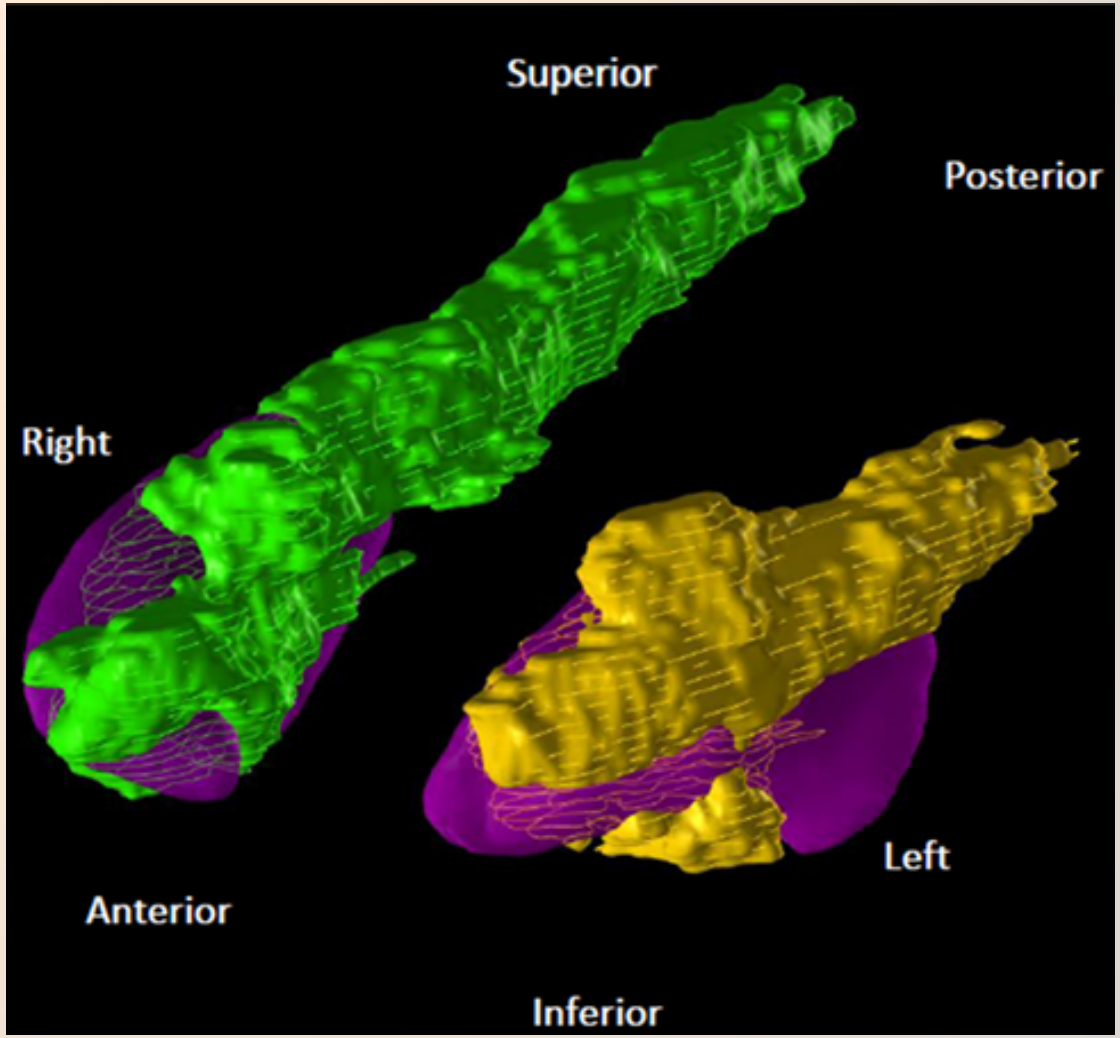
# Exploratory Endpoint - Distribution




04-Dec-2017




20-Dec-2017


# Learnings and future steps



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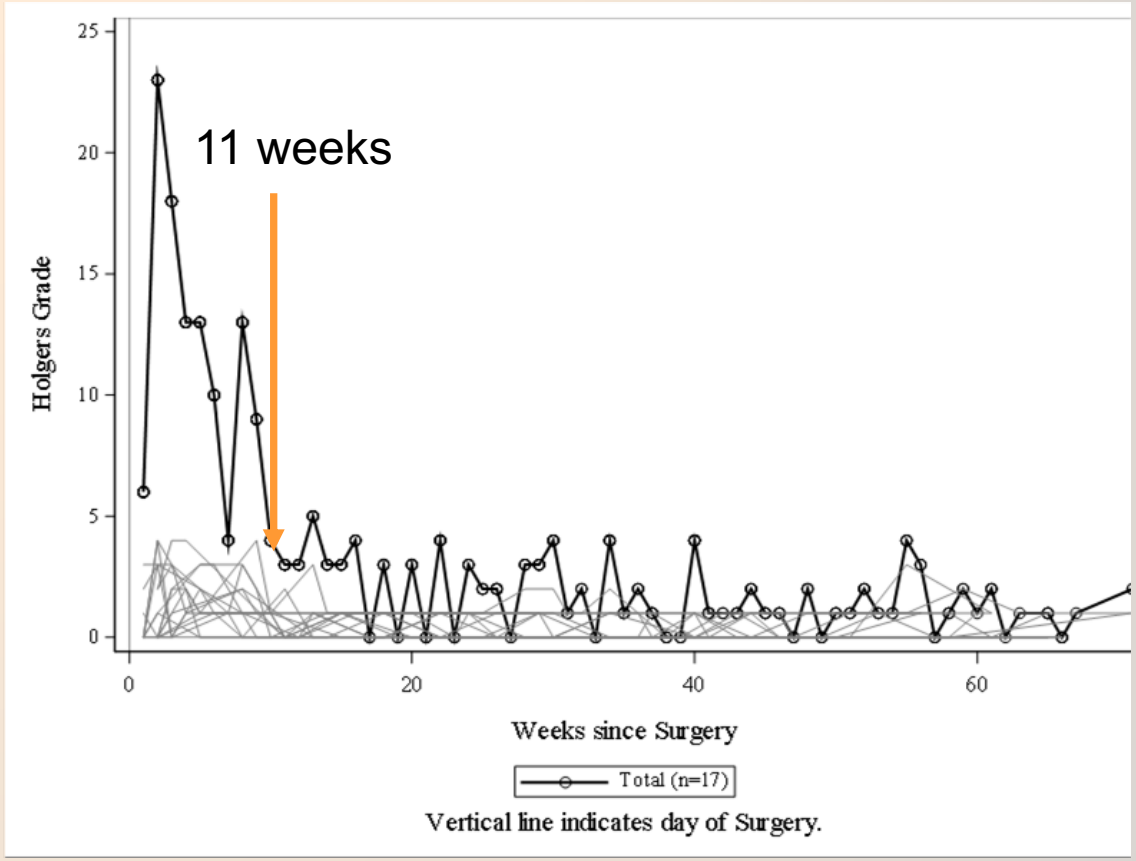
# Learnings and future steps

## Estimate of healing period for the port site

- Holger grade of 0 to 4 at each visit
- 0 = no skin reaction, 4 = worst reaction

| Healing time (Days) | |
|---|---|
| Average | 11 weeks |

**Holgers Grades (added up) vs. days since surgery**



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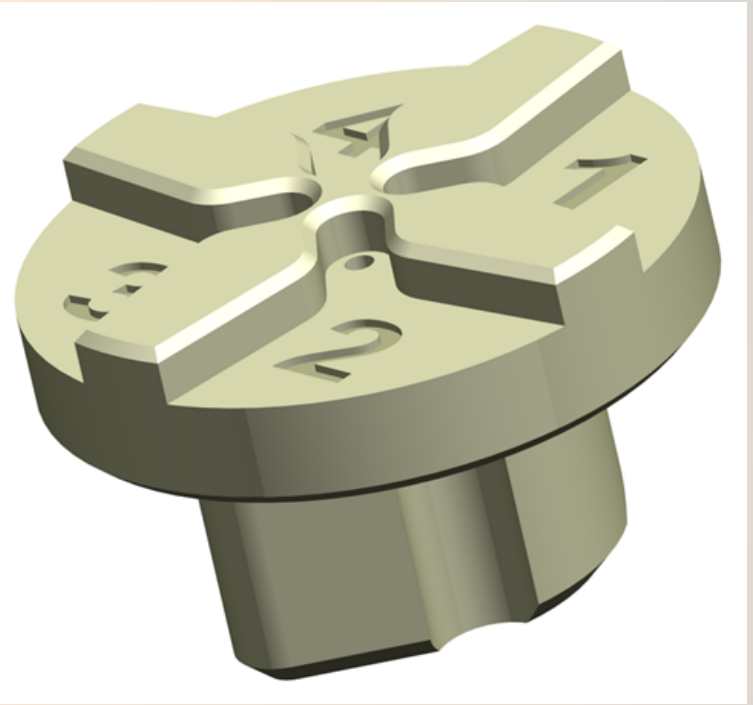
# Learnings and future steps

## Priming Aid

- **Air bubbles**
  - Improving priming (removal of air in lines) and usability







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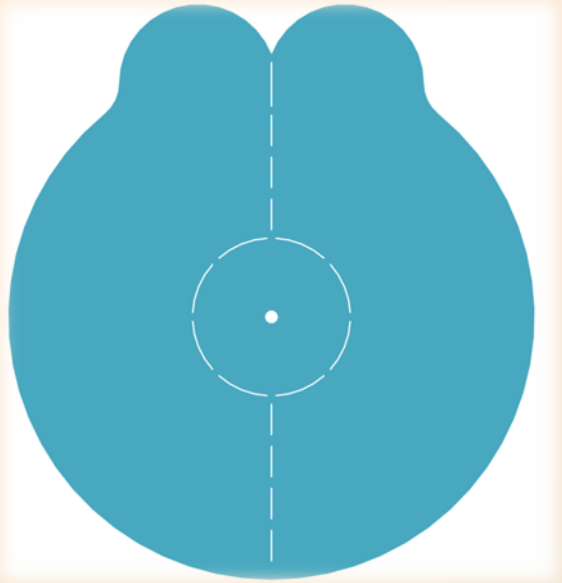
# Learnings and future steps

## Port drape

- Help to keep hair out of the way during connection of the giving set

- Help in keeping the port area generally cleaner during infusions





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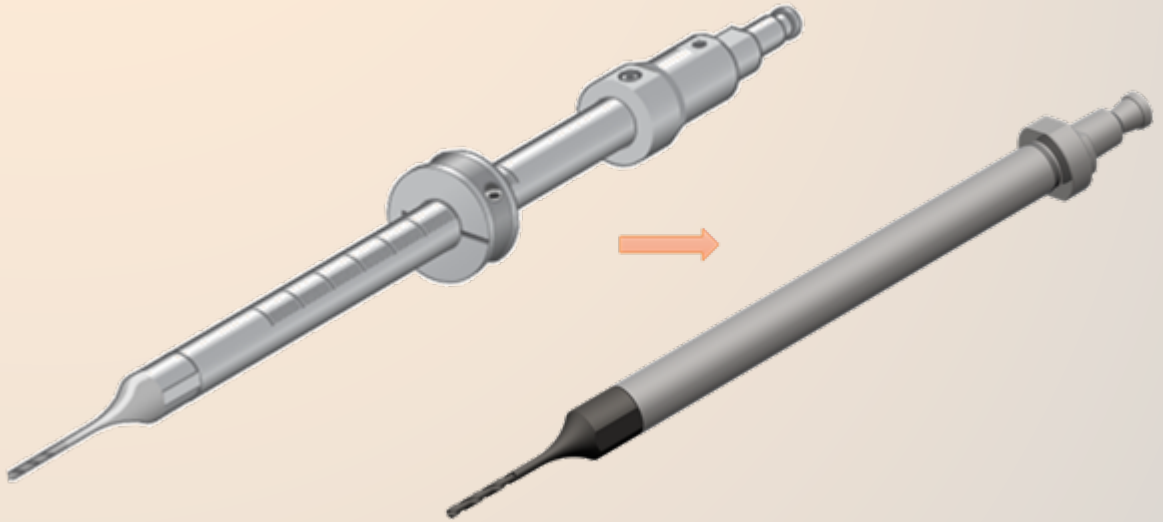
# Learnings and future steps

## Process Guidance Software (PGS)

## Surgical Instrumentation improvements





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# Learnings and future steps

## Training Manual

Includes

- Port care chapter
- Case studies
- Better planning of port location
- Importance of a ‘Clinical Microbiologist’



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# Learnings and future steps

## Instructions For Use

- Consideration on what to do if the skin is swollen during infusion
- Cleaning regime of port before an infusion clarified and made more robust
- Time between surgery and first infusion increased by one week
- Port cap wearing updated to 12 hours on / 12 hours off
- Port caps to be changed each month
- More explicit in ‘pushing the catheter right in’
- Improved Patient leaflet for port care



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# Conclusion

- Trial proved the device is safe
- Catheters hit the target
- Learnings from trial implemented either within the trial or for future trials



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# Thank you



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