









# When to think about Japan: Hindsight is 20/20

| Situation   | Risk  | Extra investment or lost of opportunities | Time to market lag |
|---|---|---|--------------------|
| <ul style="list-style-type: none"><li>• After successful EU &amp; US launch</li><li>• Meanwhile not preparing for Japan</li></ul> | <ul style="list-style-type: none"><li>• Original staff are gone</li><li>• Test reports are not sufficient</li><li>• Studies are not GCP compliant</li></ul> |   |                    |
|   |   |   |                    |
|   |   |   |                    |

Evaluate:

Direct, Distributor or Hybrid

- i Does your product fill in an unmet clinical need?

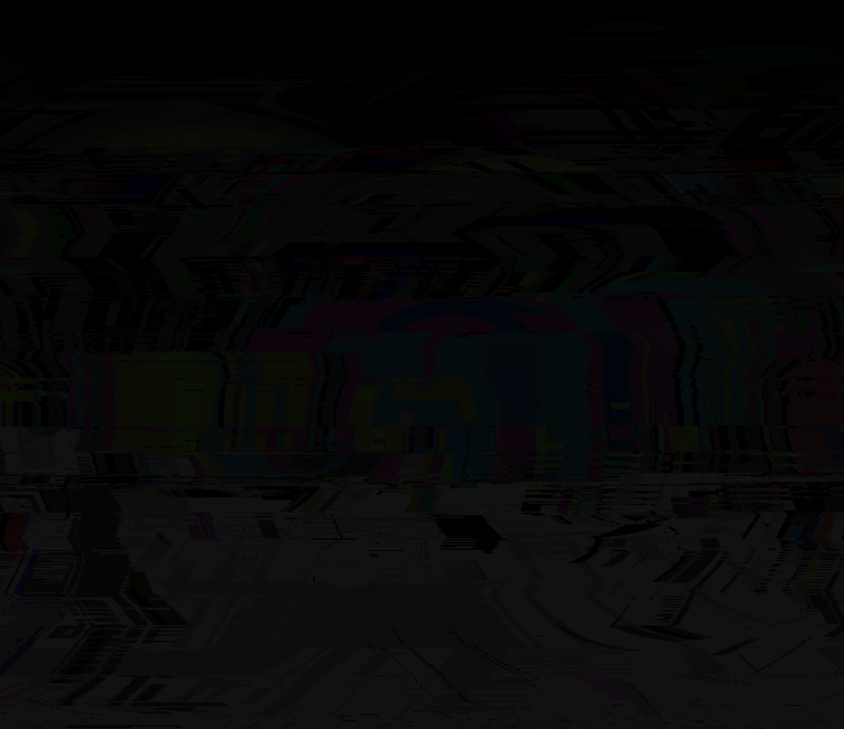








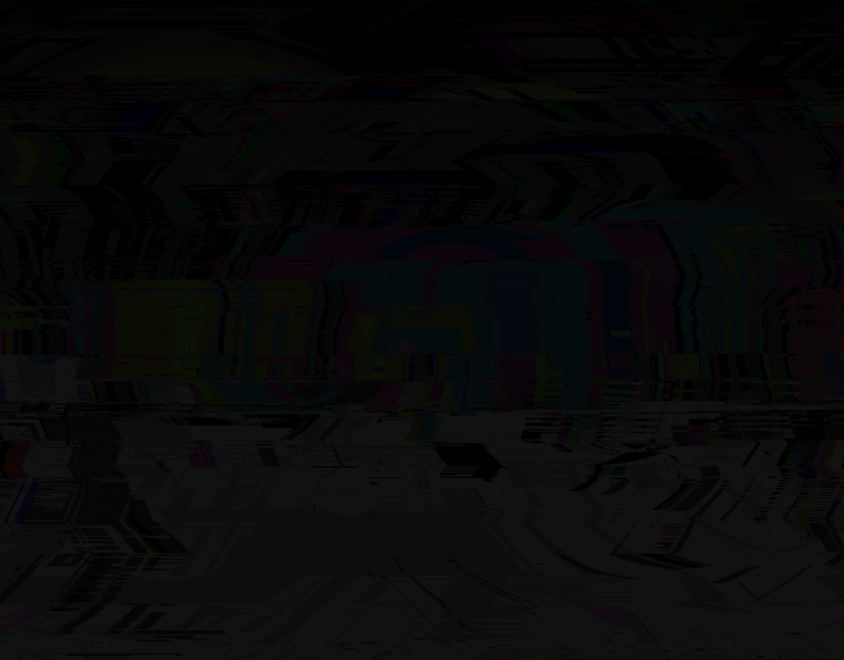
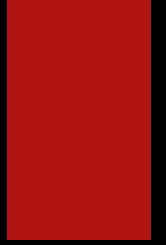
# Unmet Clinical Need Device



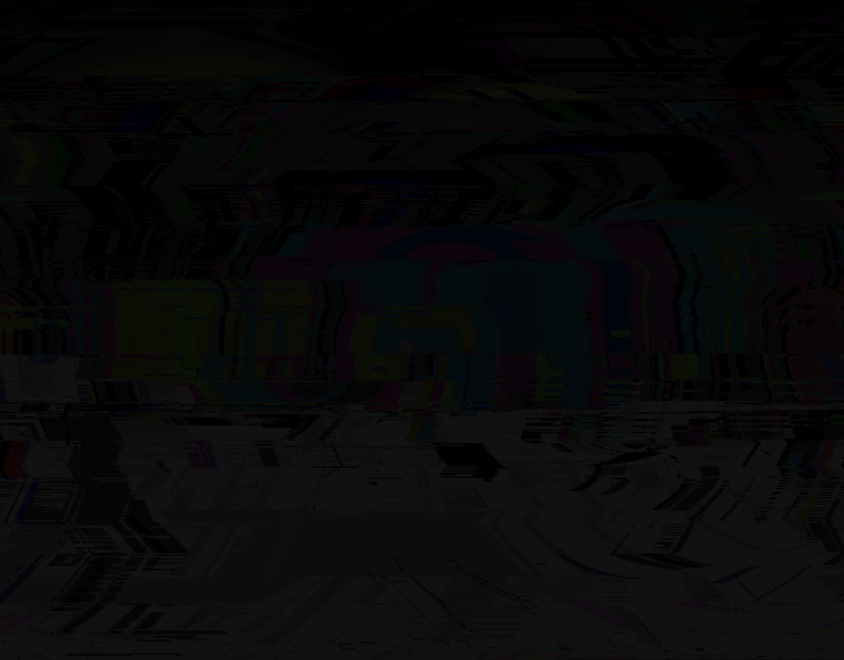
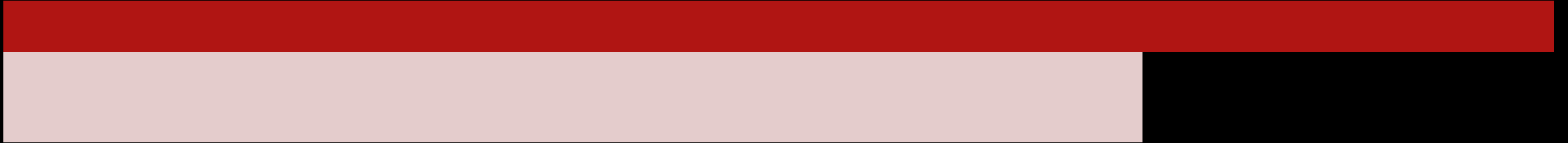
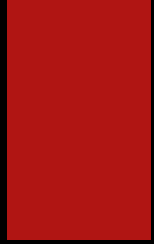




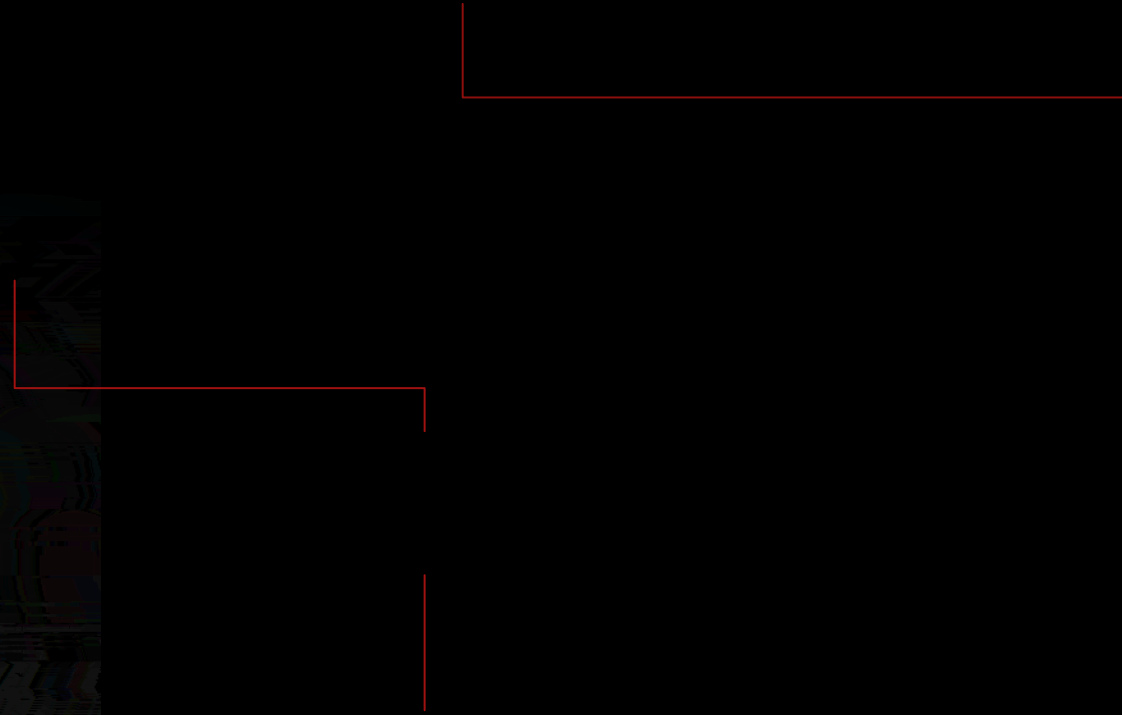
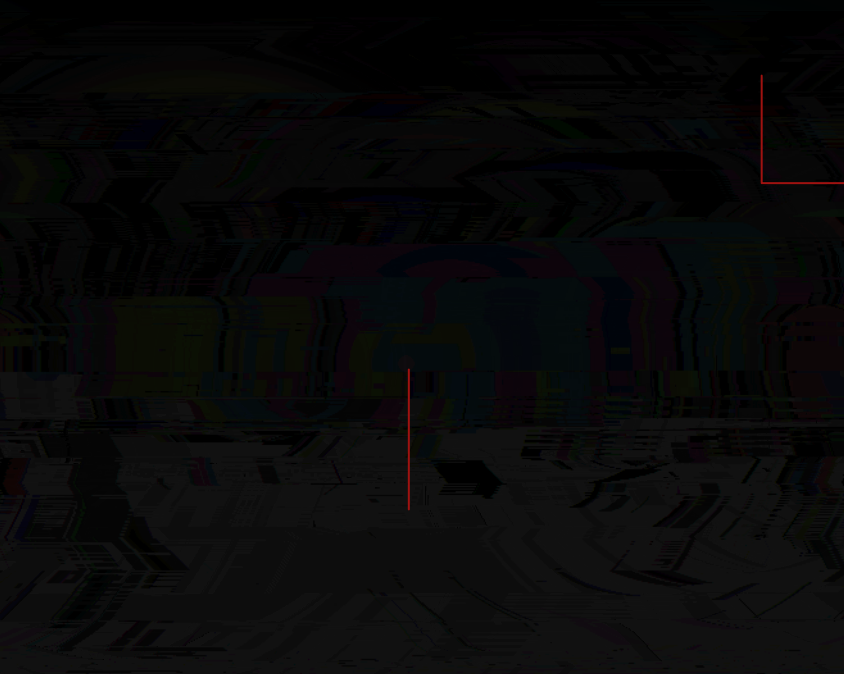
# Step 2: Think Reimbursement



# Device Reimbursement



# Decision Tree on Reimbursement











# Key takeaways

- i Think about Japan NOW





