Put a dot where you think we are today.

DHT-Derived Novel Endpoints in Pivotal Trials: Where Are We?
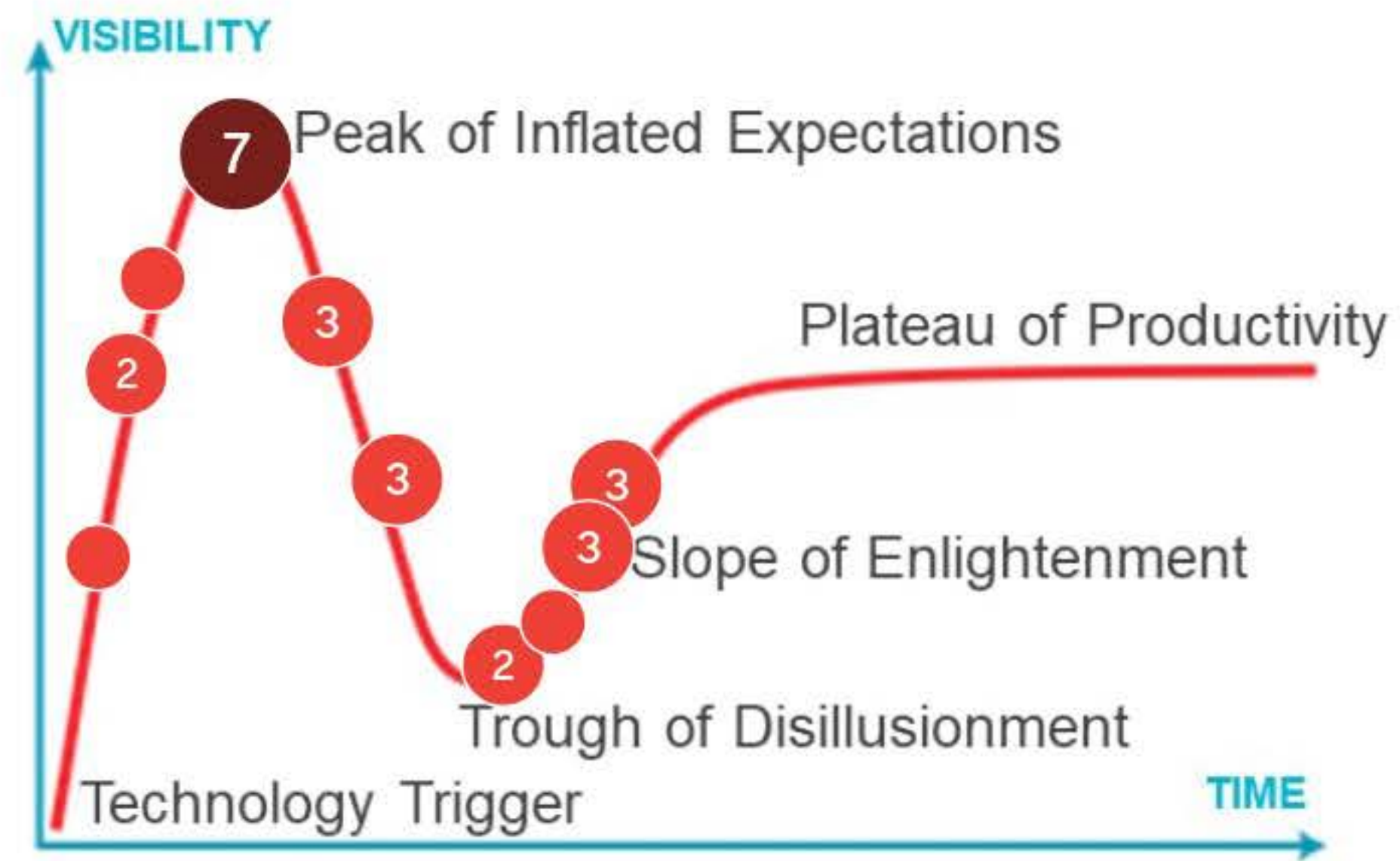
https://www.gartner.com/en/documents/3887767

Breakout Facilitators Only: List your stakeholder group and your group's top 3 barriers to the adoption of DHT-derived endpoints in pivotal trials.

Stakeholder: Patient and academia: 1. Lack of collaboration around publically available info; 2. Uncertainty on whether the measure is meaningful;3. Digital exclusion

The amount of work in terms of regulatory steps, variety of patients and cohorts, evolution of technology to maintain consistency

GOVERNMENT: 1) Lack of examples of where DHTs have shown additional benefits over traditional endpoint for patient benefit; 2) Do the new measurements add variability or reduce it; is the new measurement more precise?;...

Industry Group: Lack of clear frameworks to use (not modular, lack of building blocks; Lack of clear agency guidelines (incomplete information), multi-faceted validation process (data, device, internal, external)

Alignment on strategic priorities at the executive level between multiple stakeholders and competing priorities in conducting clinical trials

GOVERNEMNT: ...3) Lack of understanding of how a DHT-endpoint relates to a meaningful concept of interest to patients?

Gap between technology / clinical / pharma companies on priorities / strategic imperatives / needs (requires more market researches, stakeholders' interviews, ...)

Government 1. Uncertainty/lack of clarity around "is this fit-for-purpose"?; 2. Data management/algorithms; 3. The added value is not clear

lack of collaboration; lack of guidance by health authorities; challenge to get stakeholders together within companies

Breakout Facilitators Only: List your stakeholder group and your group's top 3 barriers to the adoption of DHT-derived endpoints in pivotal trials.

INDUSTRY : 1. Amount of work to make it happen; 2. Importance of executive alignment between stakeholders; 3. Gap between tech / clinical / pharma companies on mutual understanding

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What or who do you feel plays the biggest role in unlocking the adoption of DHT-Derived Endpoints?