

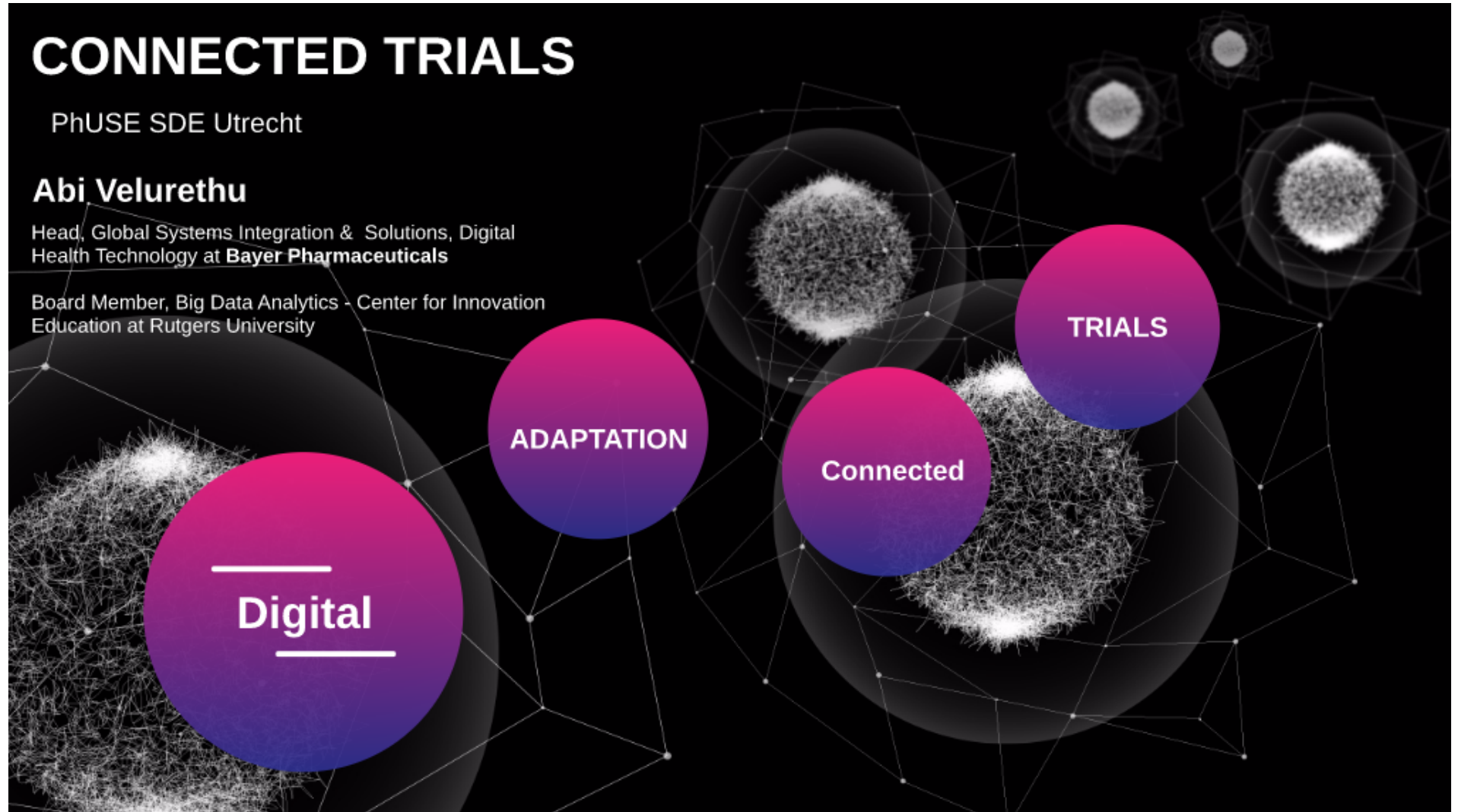
CONNECTED TRIALS

PhUSE SDE Utrecht

Abi Velurethu

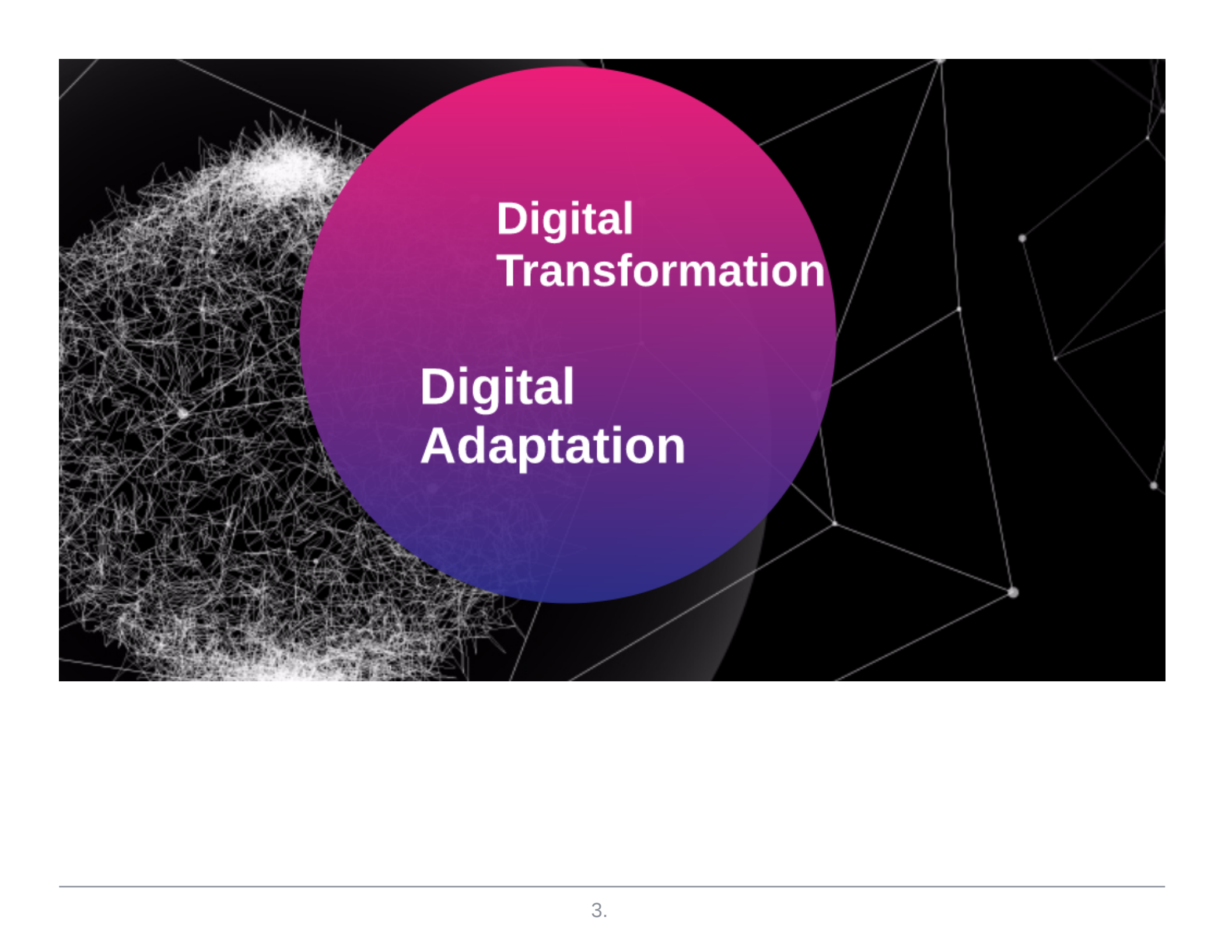
Head, Global Systems Integration & Solutions, Digital Health Technology at **Bayer Pharmaceuticals**

Board Member, Big Data Analytics - Center for Innovation Education at Rutgers University



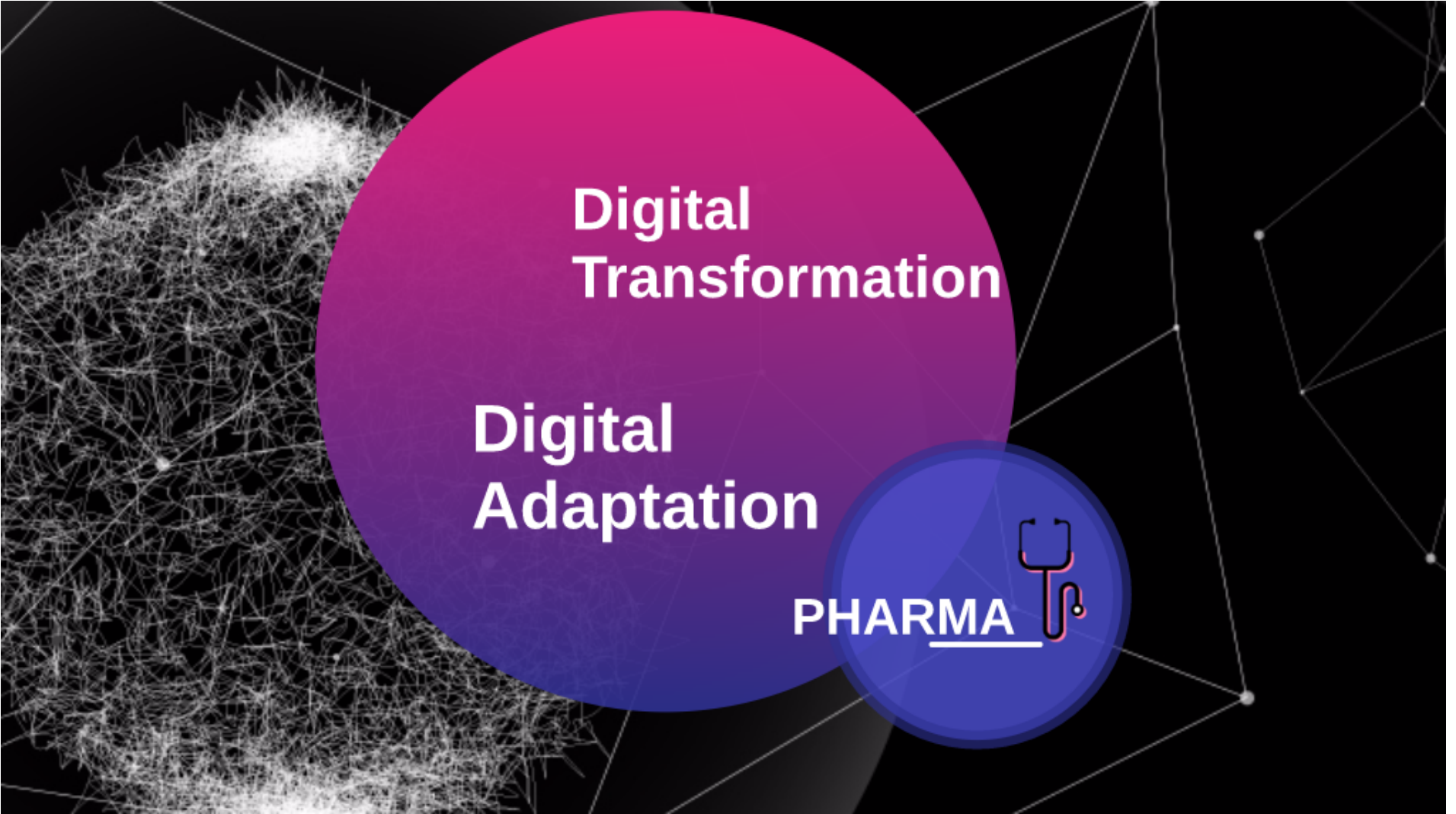


Digital Transformation



**Digital
Transformation**

**Digital
Adaptation**



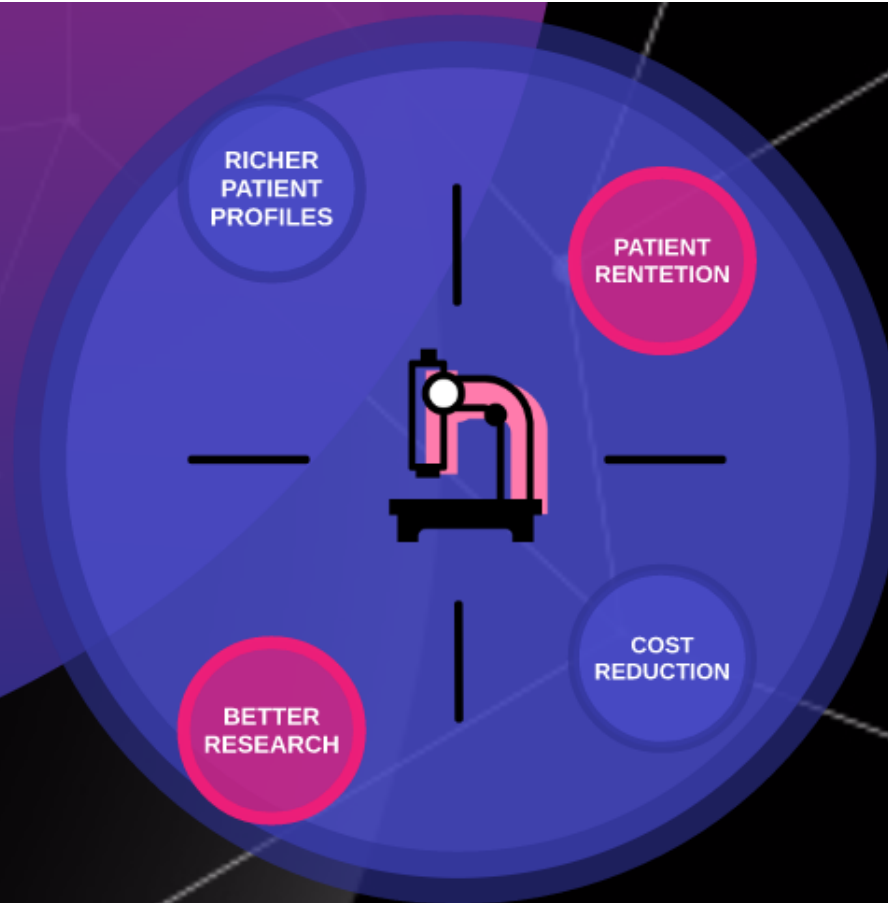
**Digital
Transformation**

**Digital
Adaptation**

PHARMA



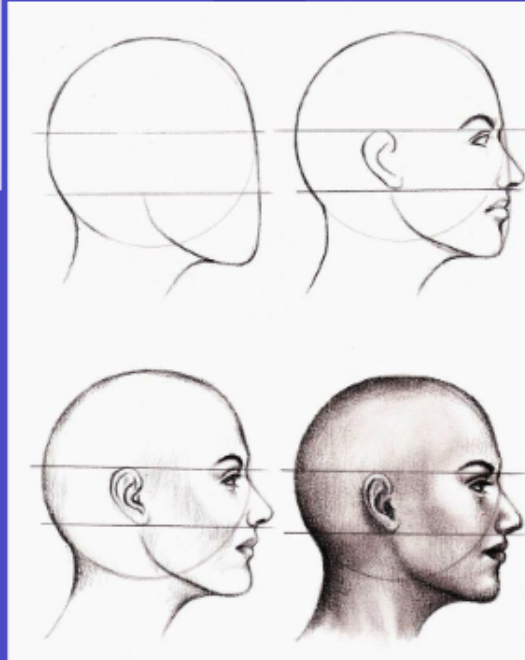
BENEFITS





RICHER PATIENT PROFILES

- Continuous Measurement
- Real World Setting
- Daily Routines



There is a potential to bring a benefit of better clinical research, safety, compliance, and efficacy

- Actionable Alerts
- Compliance
- Encouragement
- Communication

PATIENT RETENTION



Improvement in patient retention by generating actionable alerts, encouraging compliance, facilitating patient-physician communication

COST REDUCTION



- Facility Visits
- More Data
- Short Period

May reduce costs by decreasing the need for facility visits,
and due to the ability
to collect more data in a short period

BETTER RESEARCH

Better
Compliance



=

Better
Data



=

Better
Results



There is a potential to bring a benefit of better clinical research, safety, compliance, and efficacy

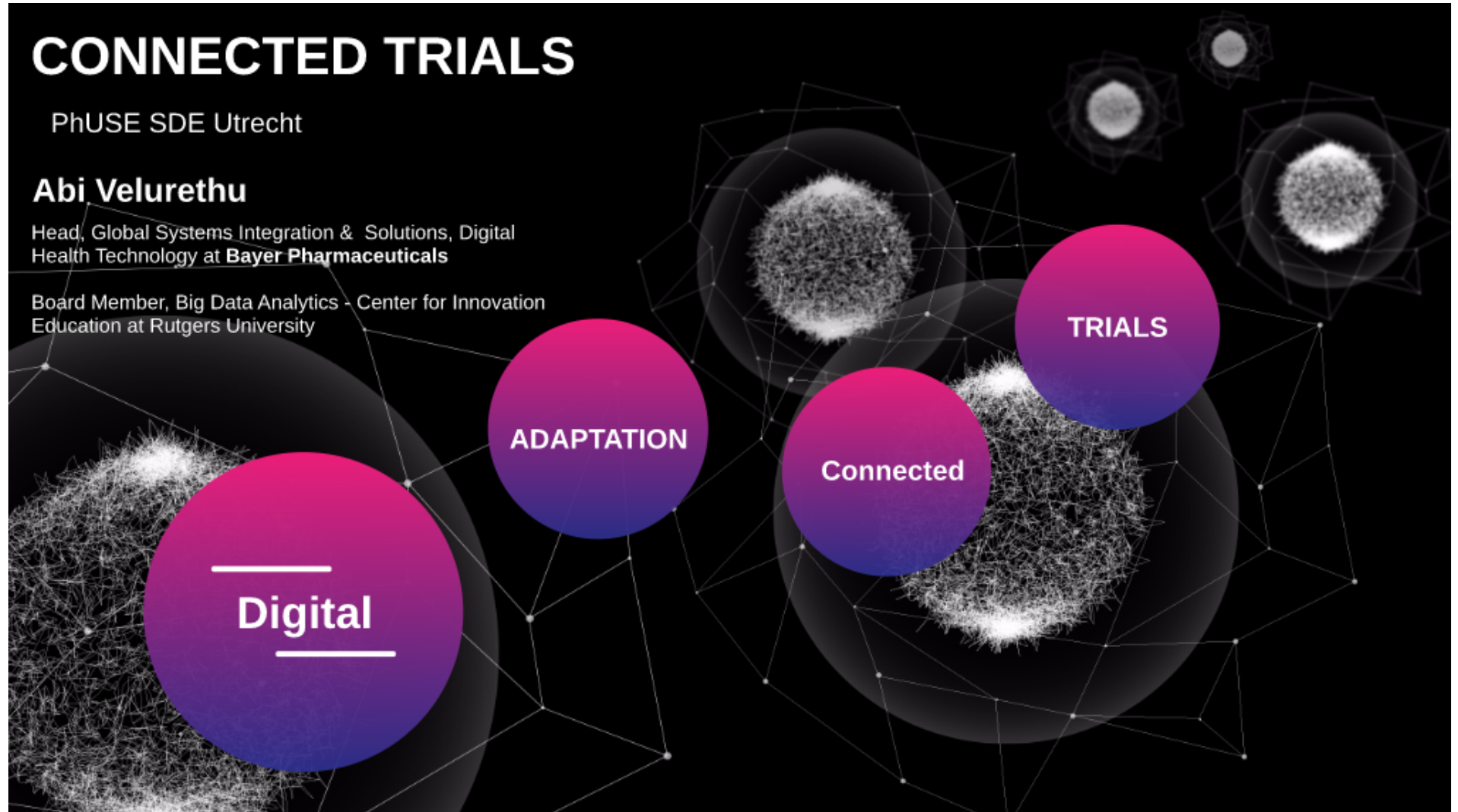
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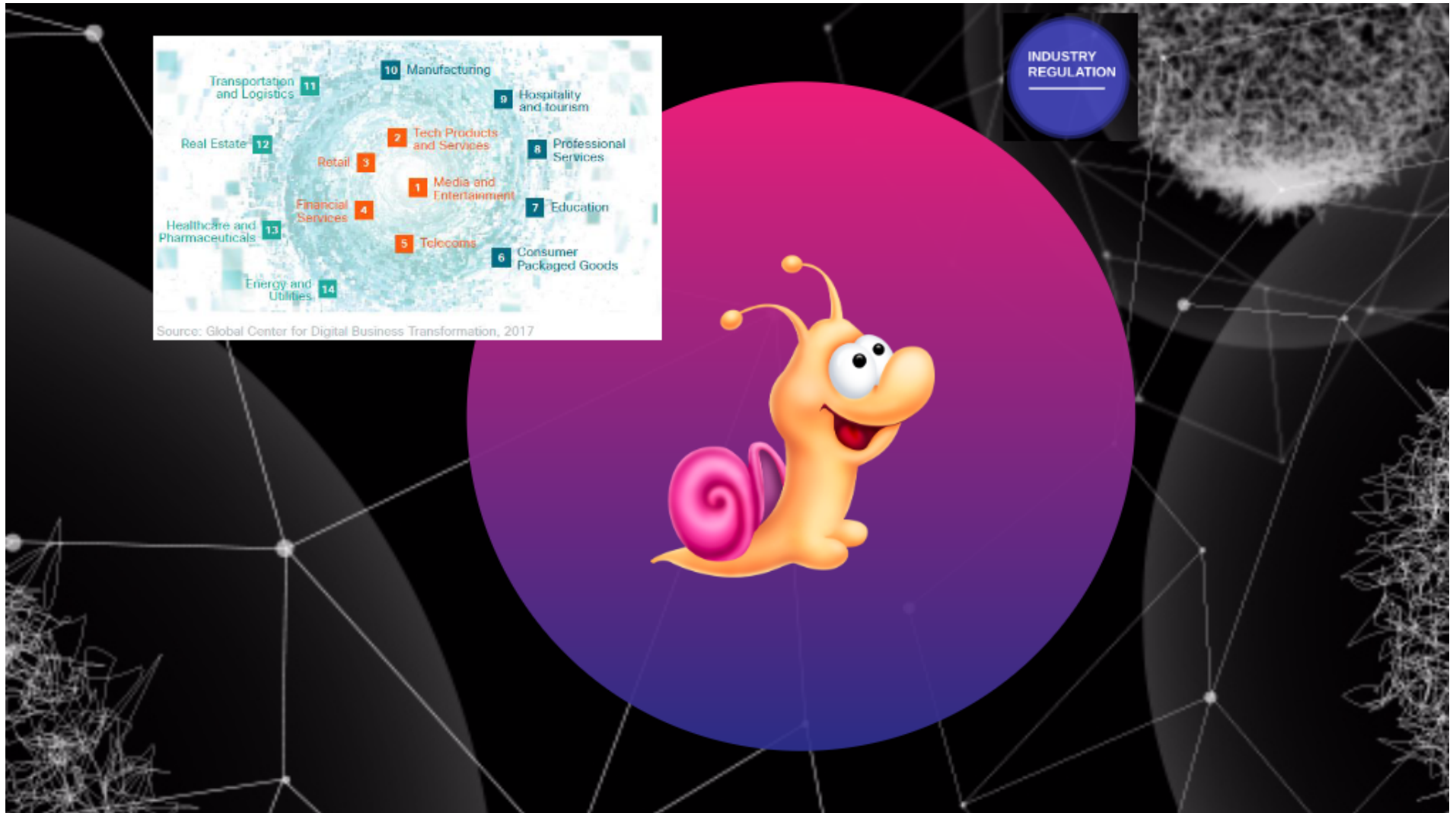
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INDUSTRY
REGULATION

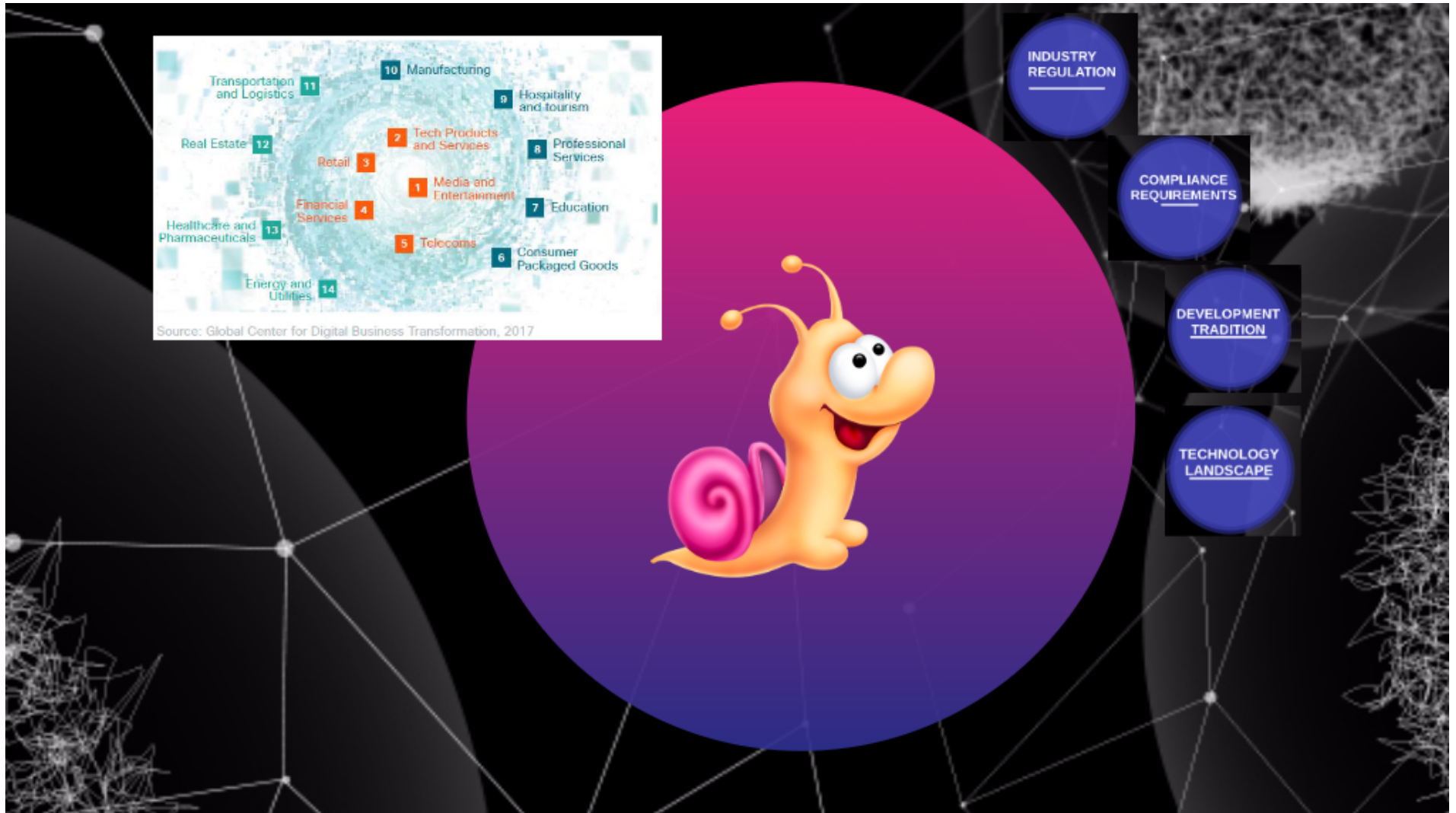
COMPLIANCE
REQUIREMENTS

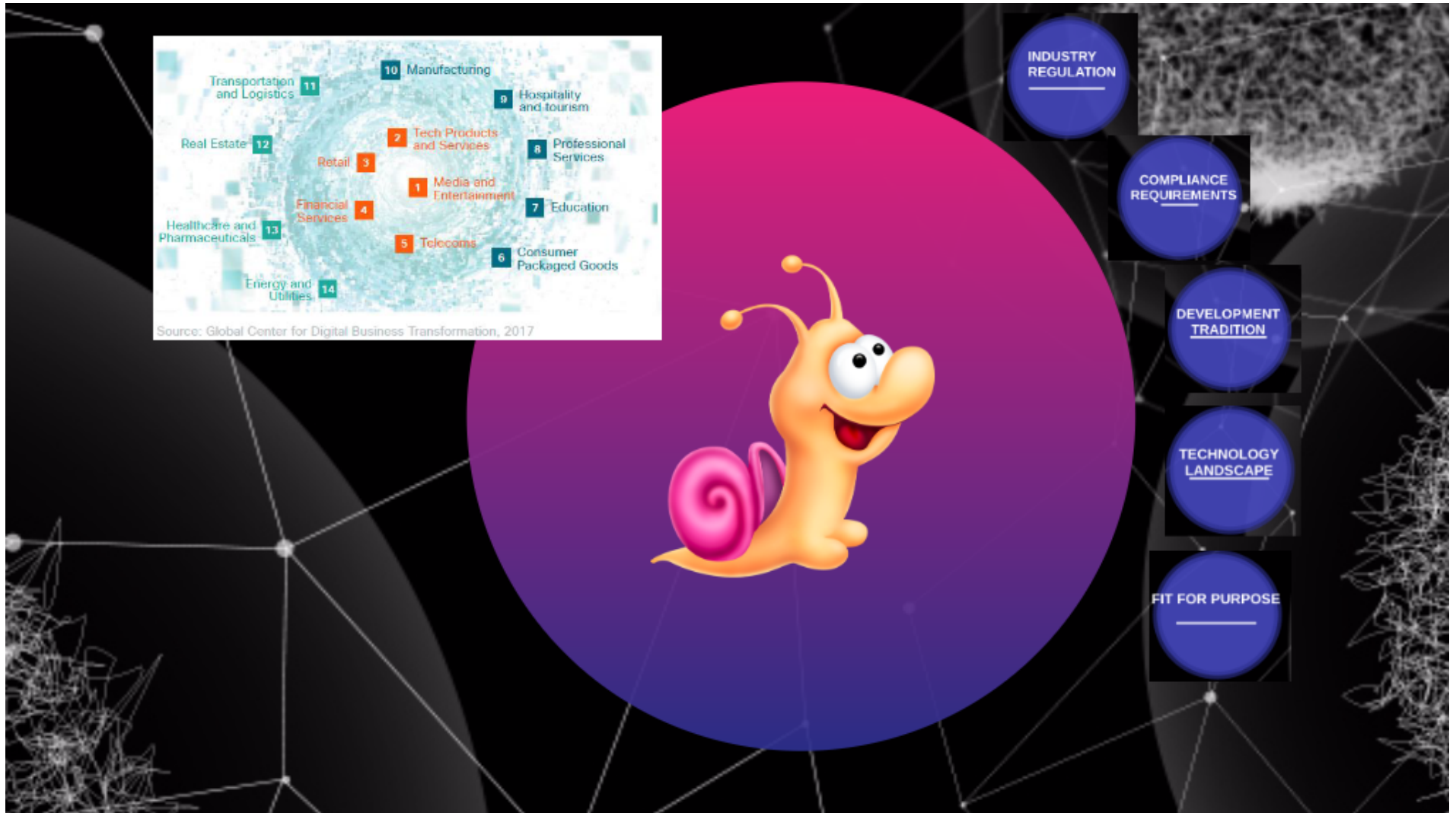


INDUSTRY
REGULATION

COMPLIANCE
REQUIREMENTS

DEVELOPMENT
TRADITION







INDUSTRY
REGULATION

COMPLIANCE
REQUIREMENTS

DEVELOPMENT
TRADITION

TECHNOLOGY
LANDSCAPE

FIT FOR PURPOSE

TRUST

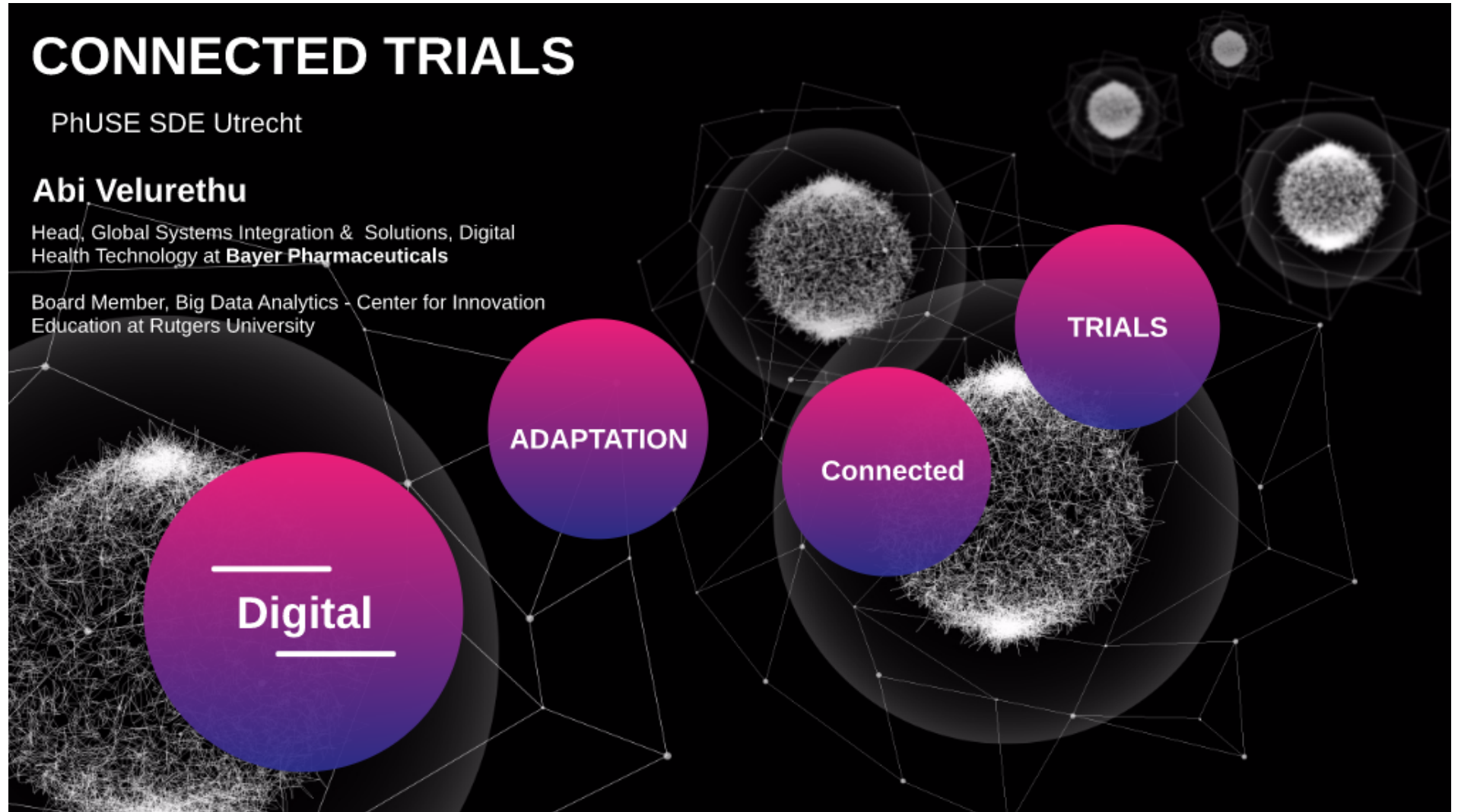
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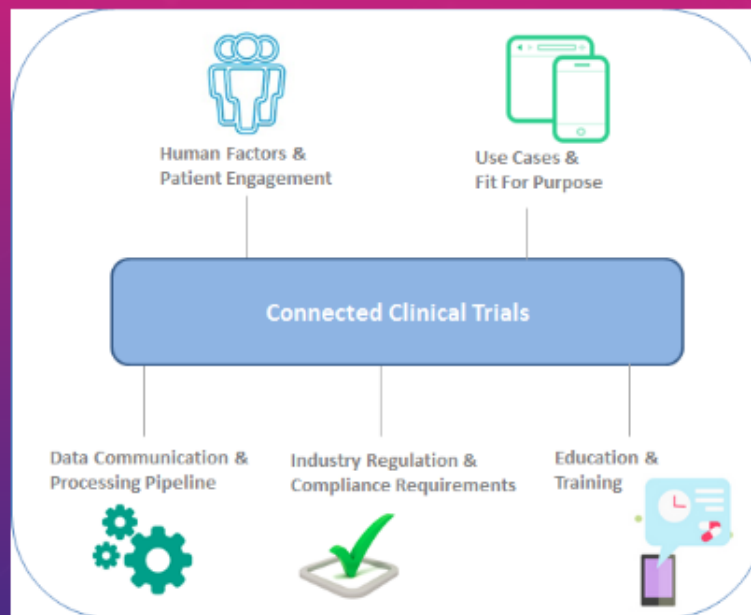
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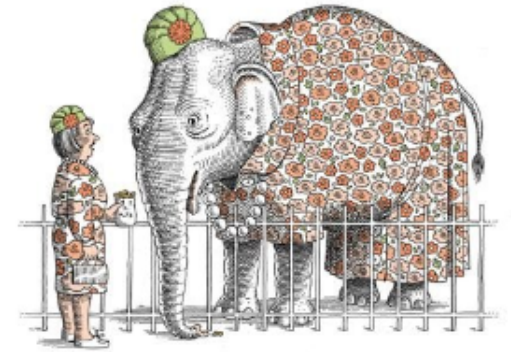
Connected



mHealth
Gateway

Human Factors & Patient Engagement

**and most of all,
because
it might be
very
embarrassing.**



Use Cases & Fit For Purpose

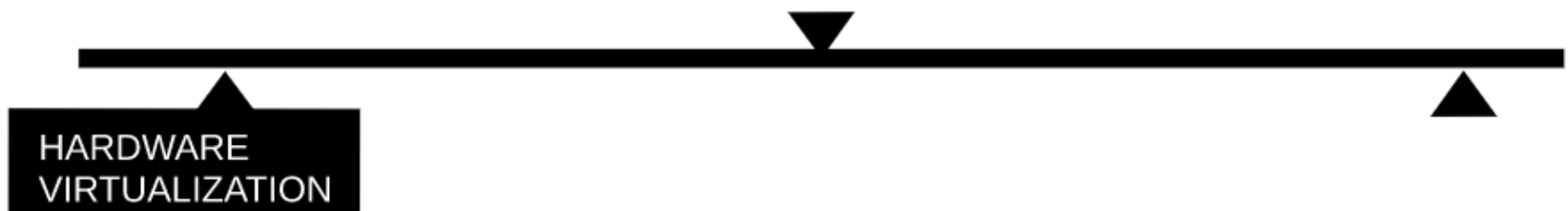


- **Identify the unique need for the clinical trial:**
 - o What data should be collected?
 - o What are the needs of the sponsors, the sites, and, particularly, the patients?
 - o How will the data be used?
 - o How will the data be incorporated into standard event reporting practices?
- **Learn the disease conditions:**
 - o What are patients' daily routines?
 - o Would the device help them cope with disease or would it be burdensome?
 - o Is there a possibility that the trial outcome might be influenced by the use of devices?
- **Engage patient advocacy groups:**
 - o What are the patients concerns with using the device in the trial?
 - o Would one device (e.g. touch, feel, color) be better over another?
- **Understand the technology involved in the trial:**
 - o What are the use indications that the device is cleared for?
 - o How are the measurement artifacts dealt with?
 - o What are the device failure modes?
 - o Is there enough information in the system to ensure data integration?

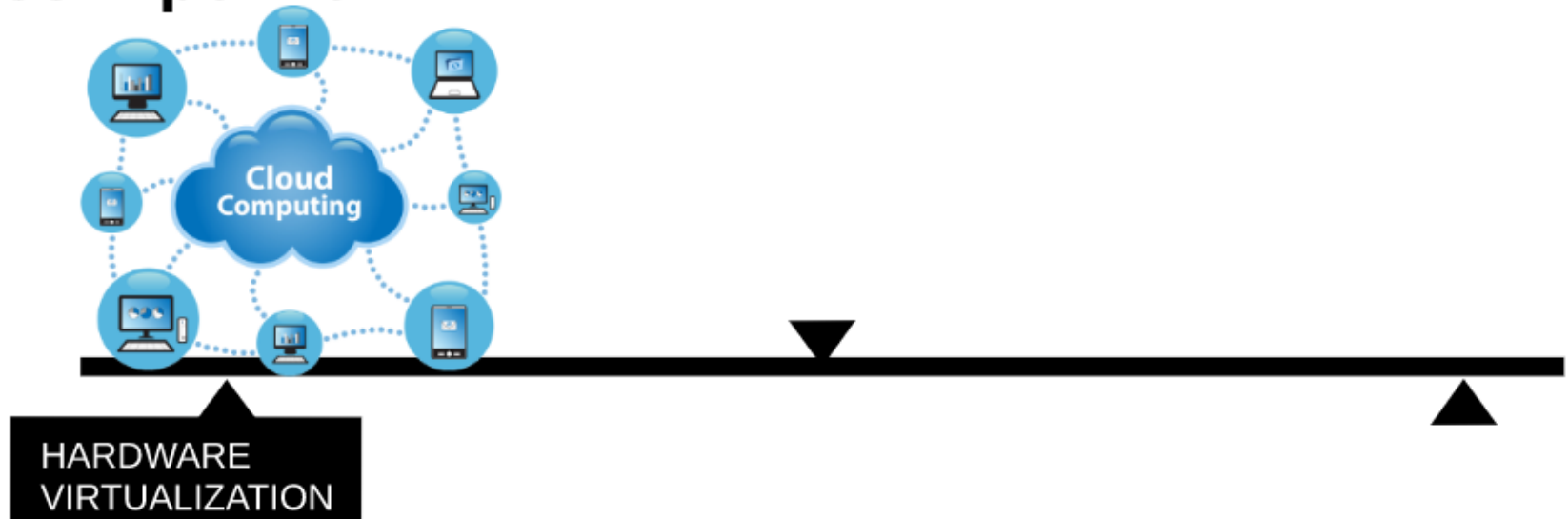
Data Communication & Process Pipeline



Data Communication & Process Pipeline



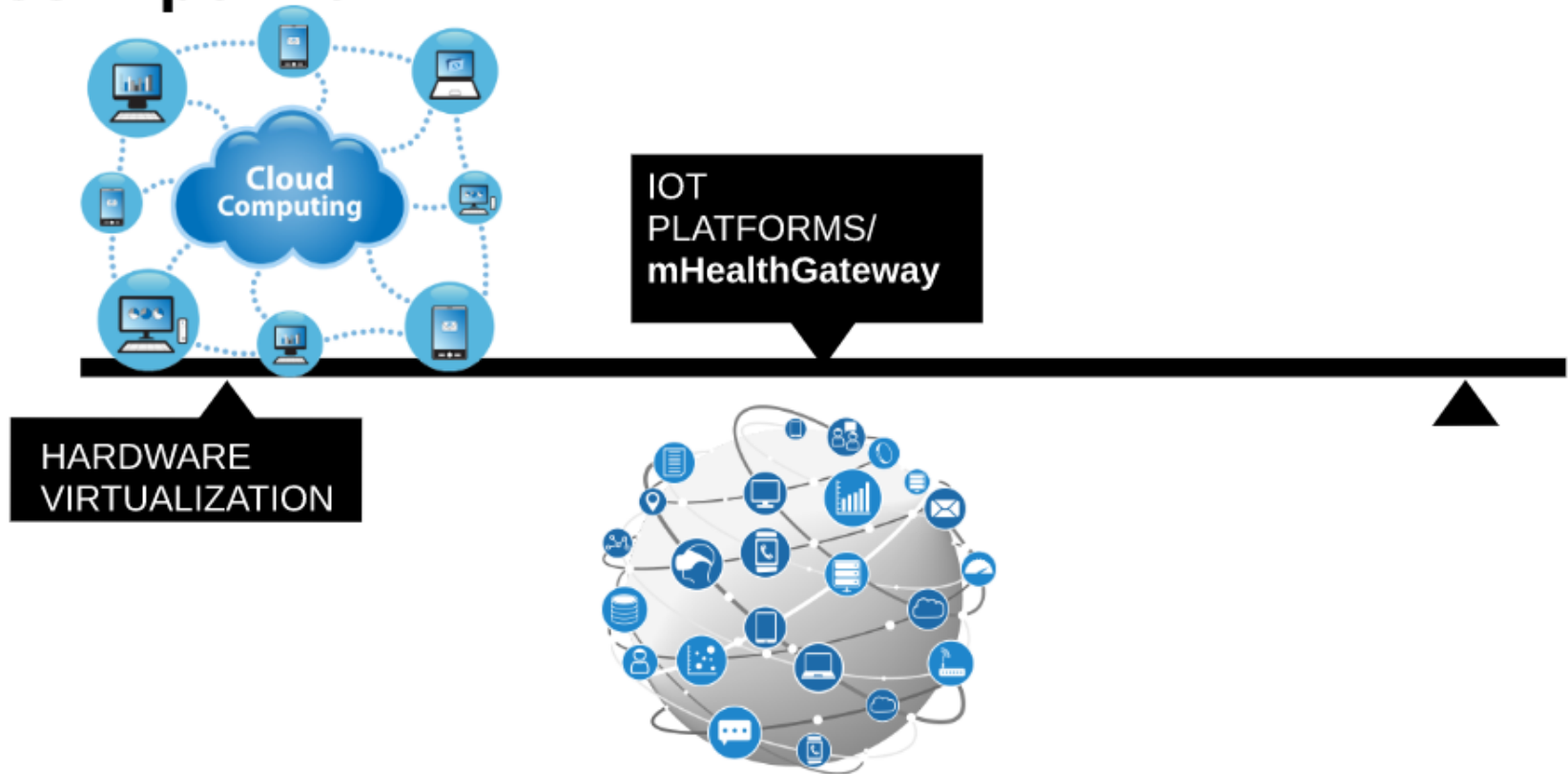
Data Communication & Process Pipeline



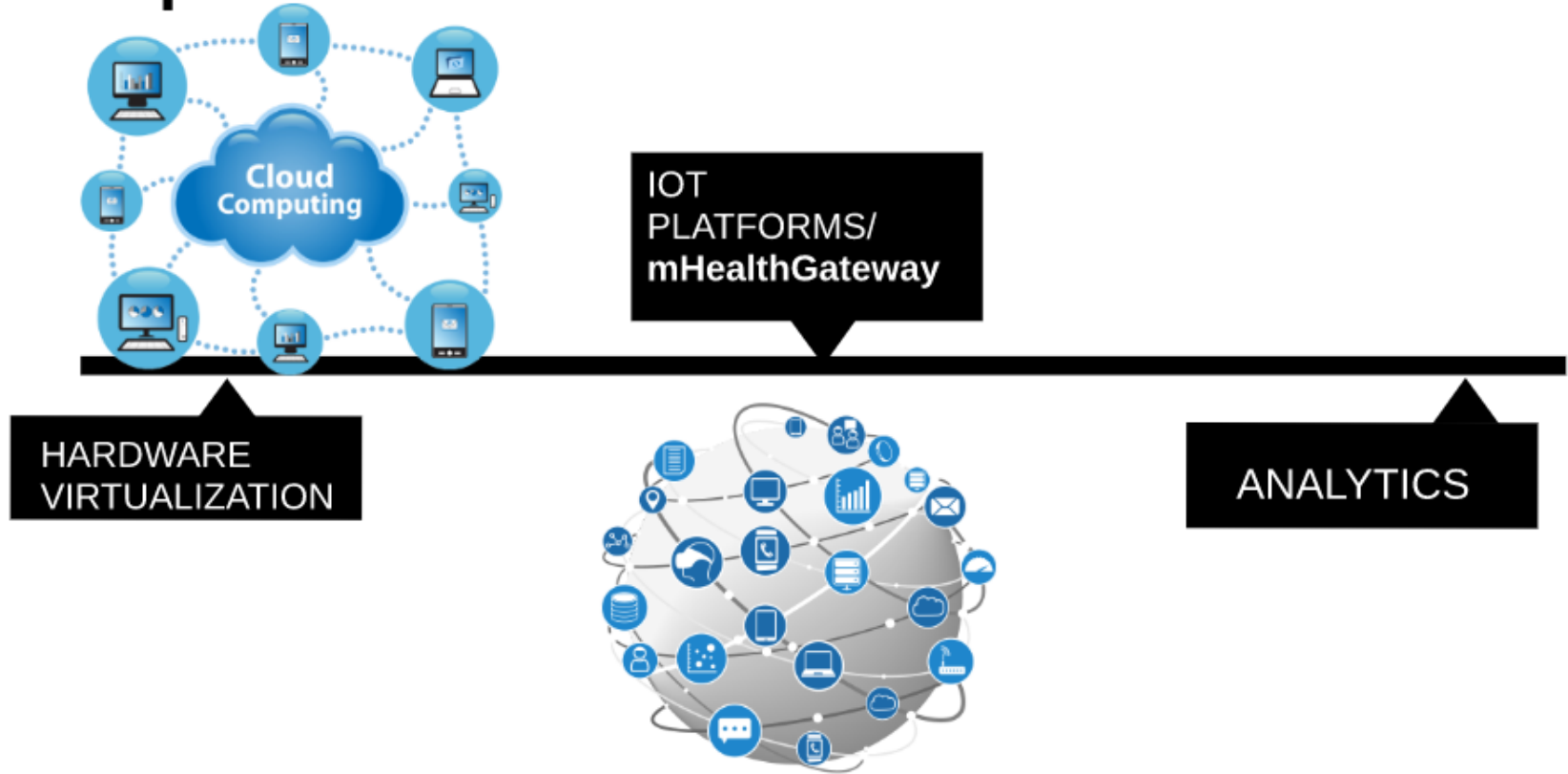
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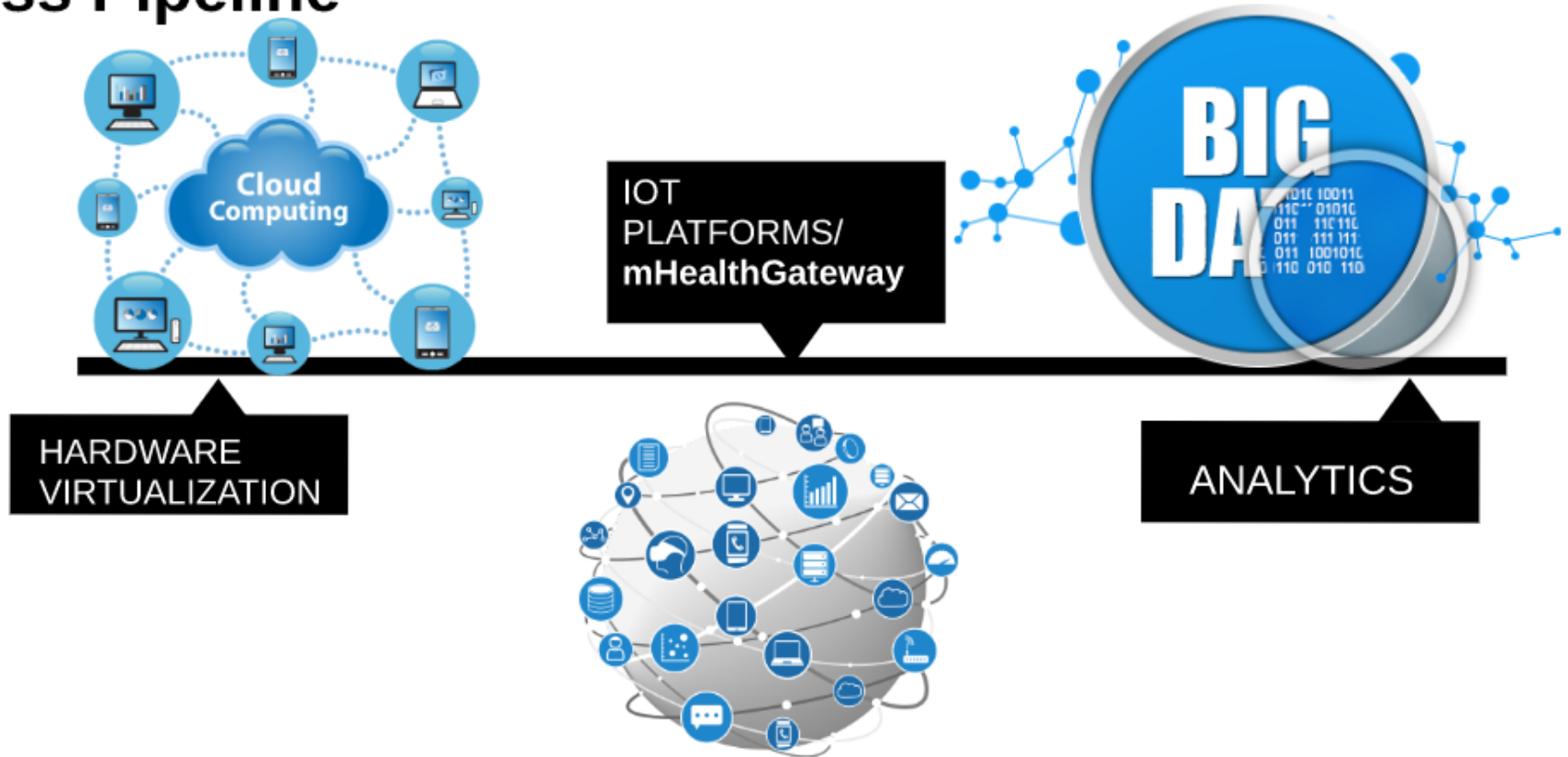
Data Communication & Process Pipeline



Data Communication & Process Pipeline



Data Communication & Process Pipeline

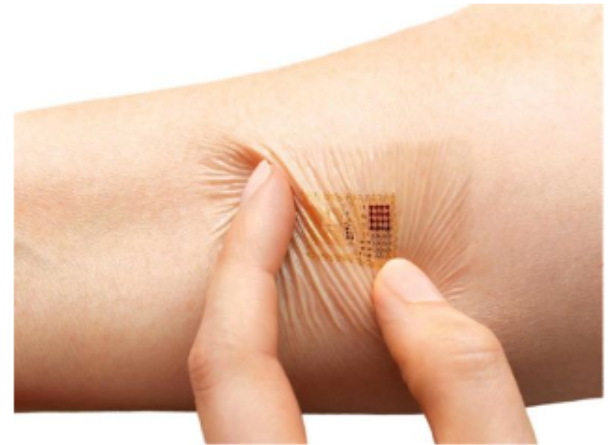


INDUSTRY REGULATIONS & COMPLIANCE REQUIREMENTS

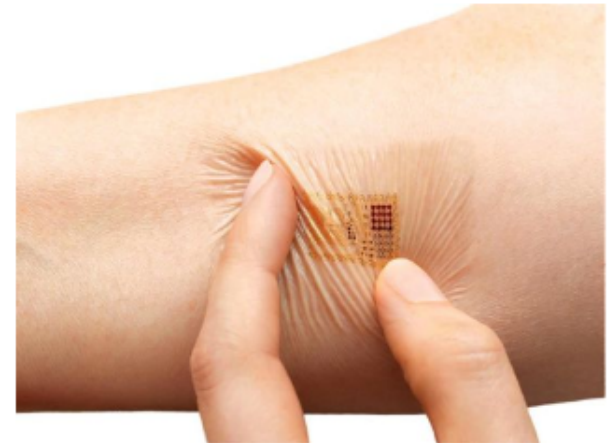
Digital Health Innovation Action Plan.



EDUCATION AND TRAININGS FOR CLINICAL TEAMS



EDUCATION AND TRAININGS FOR CLINICAL TEAMS



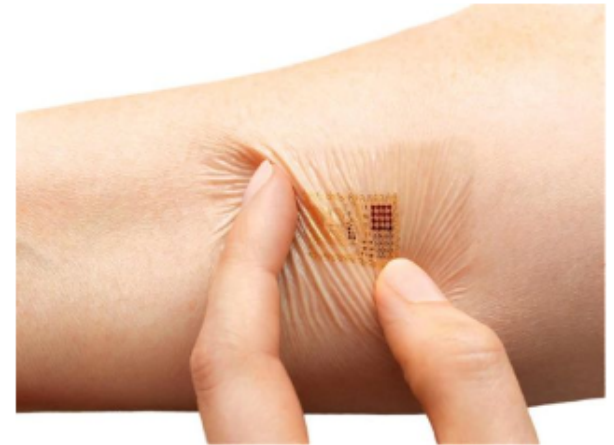
incorrect use of the
mobile devices



EDUCATION AND TRAININGS FOR CLINICAL TEAMS



indication specific
and appropriate
uses



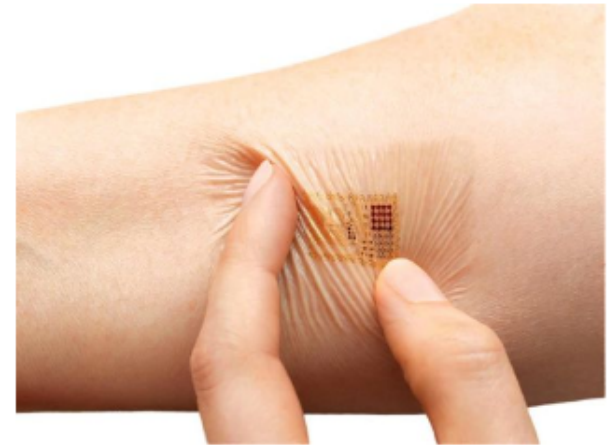
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EDUCATION AND TRAININGS FOR CLINICAL TEAMS



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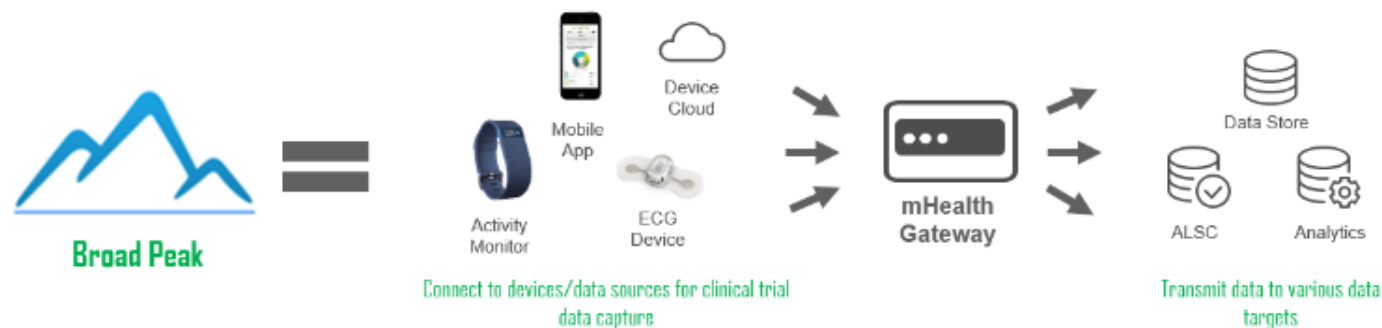


the device care,
tolerance, and
dependence

mHealth Gateway

mHealth Gateway Project Scope

focuses on ingesting and transmitting mHealth data



The Broad Peak is a critical part of the Mountain View Program aiming to develop and acquire an enterprise level gateway solution to enable:

- Ingestion of data from various data sources in a clinical trial (device, device cloud, mobile application)
- Transmission of data through the gateway
- Delivery of data to end-points in Bayer's technology landscape

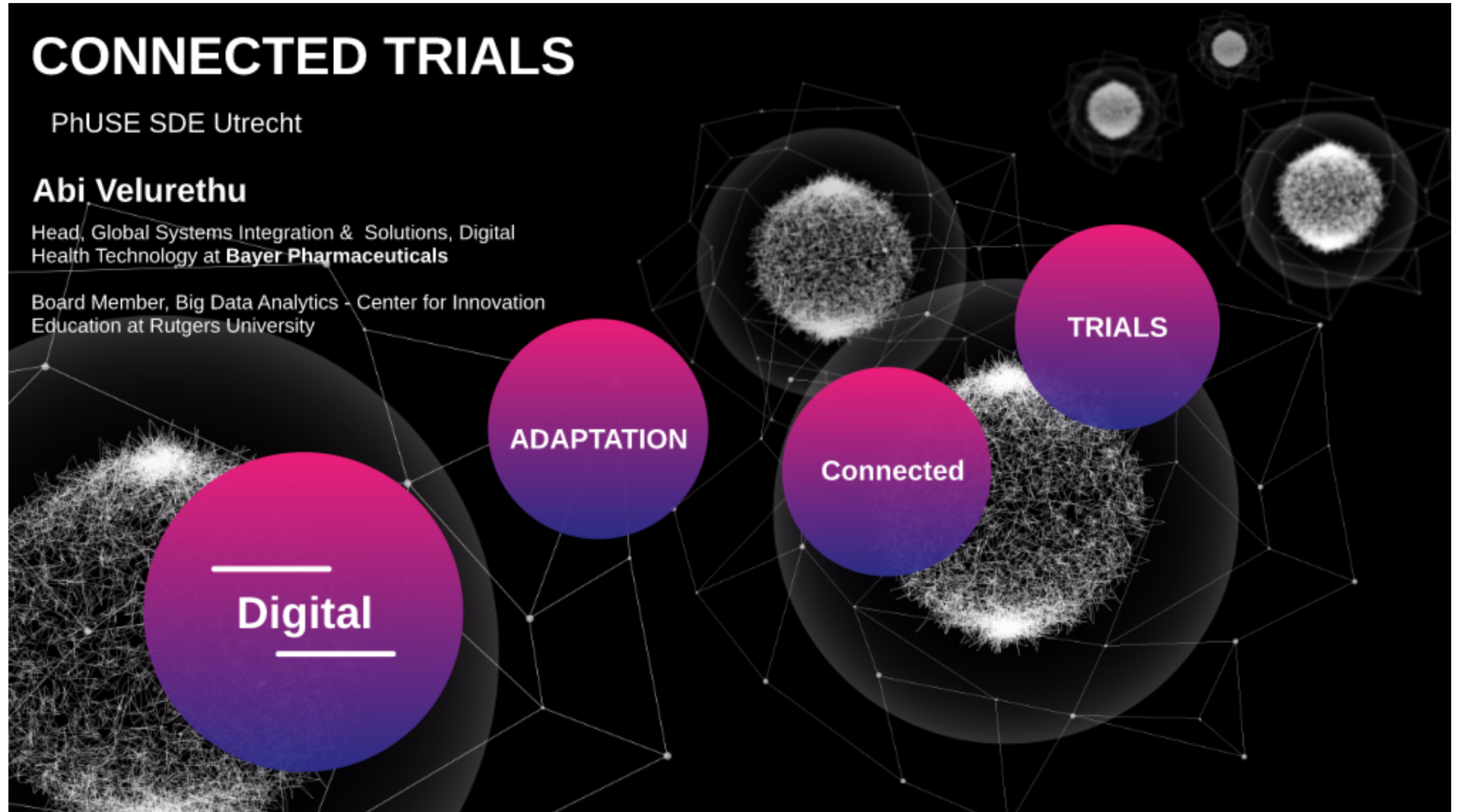
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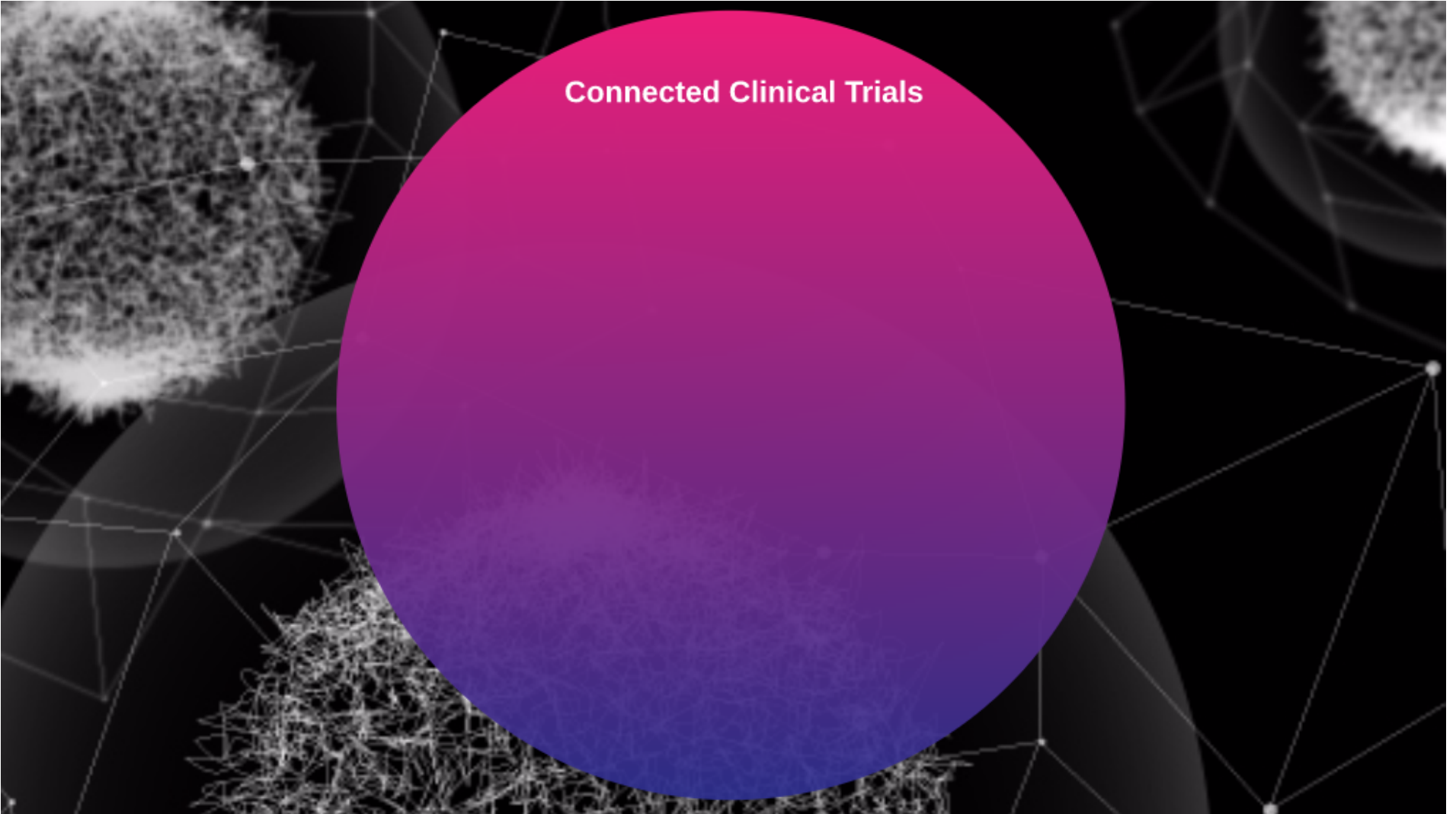
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Connected Clinical Trials



Connected Clinical Trials

DIGITAL ADAPTATION

It isn't a department

Connected Clinical Trials

DIGITAL ADAPTATION

It isn't a department

Nurturing a digital
culture



Connected Clinical Trials

DIGITAL ADAPTATION

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Thank You

Contact Information



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