IPSEN
Innovation for patient care

AI Guidance

June 2023

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01 What is AI?

AI vs Machine Learning vs Deep Learning

The 3 terms are often used interchangeably, but they do not refer to the same things

Artificial intelligence

Any technique that allows computers to mimic human intelligence.
This includes both Machine learning & Deep Learning

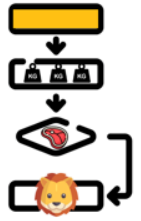
Machine Learning

Creates algorithms that can learn from data and make decisions on new unseen data based on patterns without being explicitly programmed.
Requires human intervention when decision is incorrect

Deep Learning

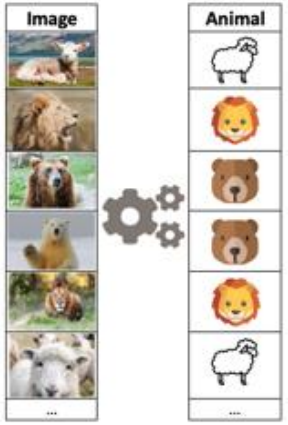
Subset of Machine learning in which models can extract information and learn from large data sets – usually applied on unstructured data such as text, images or sound

"If an animal has a beige coat, weighs 190kgs and eats meat then it is a lion."



"We have 10 years of history on animals' weights, food and color. Let's train a model to recognize a lion based on its distinctive characteristics."

"We have a million animal images in different environments, let's train a model to classify these images."



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02 Pharma use cases linked to AI

AI potential use cases in the Pharma Industry along the value chain

Illustrative – non exhaustive

Research and early development

- **Drug target identification, selection and prioritization**
- In silico[1] compound screening and design for small molecules
- Identify new biomarkers from images, genomics, RWD[4] & smart devices
- Dose/dosing regimen optimization (e.g. by predicting PK[7] profiles after drug admin)

Development, regulatory and safety

- Selection of trial participants by predicting clinical outcome
- Trial data collection, management & analysis
- Adherence/persistence monitoring (e.g., using digital biomarkers or RWD)
- Clinical endpoints assessment
- **Active safety surveillance, AEs[5] reporting classification**

Manufacturing and supply chain

- Quality exception monitoring
- **Smart monitoring and maintenance**
- End-to-end supply chain planning (e.g. product demand forecast)

Commercial & Medical Affairs

- Business insights generation
- Improve patient and customer journey
- Commercial spend optimization (e.g. mix modelling)
- Field force effectiveness (e.g. next best actions)
- **Understanding/optimizing RWD to identify patients, define targeting approaches etc.**

Relevant examples

Microsoft / novo nordisk

- In 2022, NN signed a partnership with Microsoft to **expedite the D&D[2] of drugs leveraging big data and AI** for detecting new targets and validating disease biomarkers
- In particular, the AI is sifting through mass amounts of scientific literature, patents, reports etc. to draw up analysis for researchers

SANOFI / Kap Code FROM DATA TO HEALTH

- In collaboration with Sanofi, Kap Code developed a **data analysis program**, Detec't, which screen social networks and medical forums to source PV[3] information

SEAVISION

- SEA Vision developed a **Line Clearance solution** powered by AI to automate line clearance procedures while avoiding errors, reducing the time required and improving production lines' OEE[6]
- AI algorithms analyze inspected scenes in real-time, identifying abnormalities

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- **Taz alerts:** ML model uses RWD to identify FL[8] patients in the US that could benefit from Tazverik. Previous treatments, line of therapies are used to list patients associated to an HCP that could benefit from Tazverik

Note: [1]computuer-based simulations or experiments conducted virtually, in contrast to traditional laboratory or in vivo experiments; [2]Discovery and development; 3pharmacovigilance; [4]Real world data; [5]Adverse events; [6]Overall Equipment Effectiveness; [7]Pharmacokinetics; [8]Follicular lymphoma. Sources: Pharmaceutical Technology; Kap Code; SEA Vision; FDA, using AI & machine Learning in the development of Drug & Biological products

Other AI use cases

Illustrative – non exhaustive

Purchasing & Procurement

- **Spend prediction** based on clustering of entity characteristics to identify discrepancies
- **Contract efficiency** by using NLP to identify situations where clauses are not enforced and related benefits
- **Purchasing price modelling** and identification of outliers for re-negotiation
- **Supplier performance prediction** and raise alerts on quality levels (e.g. lead times) for future supplier deliveries

Finance, Controlling & SG&A

- **Rolling P&L forecast** production by automating the data collection and processing
- **Cost modelling** by following the end-to-end fabrication process and measuring wastage at every step
- **New products costing** by learning from similar products and consider BOM[1], wastage rate, OEE, productivity etc.
- **Batch size optimization** based on complete models considering change-over costs, stock impacts

HR

- **Employees churn prediction**: identify patterns leading to churn to build recommendations
- **Employee records management** (e.g. automated detection and correction of errors in data entry)
- **Payroll processing and benefits administration**
- **Recruitment & hiring** (e.g. generation of customized sequences of communications for each candidate)
- **Employee experience monitoring** (e.g. identification of bottlenecks in workspaces)

Corporate Social Responsibility

- **Energy consumption optimization** of a building using ML models by analyzing past consumption
- **Building attendance prediction** (e.g. to optimize rooms, predict meeting rooms usage etc.) through the analysis of past frequentation and time series forecast
- **Prediction of risk of accident in the workplace** for their prevention through the analysis of previous accidents and their context

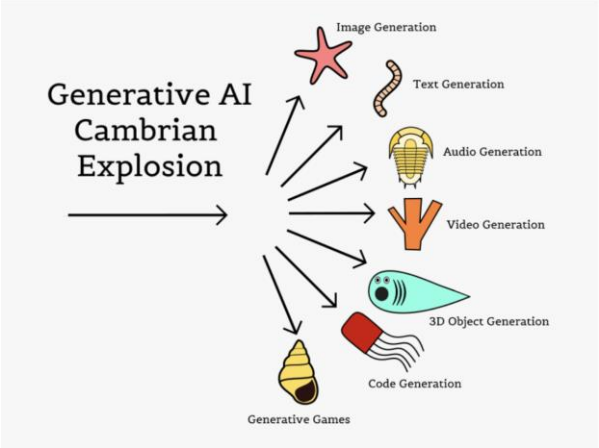
Note: [1]Bill of Materials

03 Generative AI

Generative AI Revolution – definition

Definition

- Generative AI falls under the broad category of machine learning and is a type of AI technology able to **produce various types of new content**, including text, imagery, audio, code or synthetic data
- Unlike other types of AI, in Generative AI we want more than only predicting a target (cat or dog) given some features (image)
- We want the model to **learn the underlying structure of the data** (image of cats) **to generate new unseen data** (new photo of a cat)



Training Data

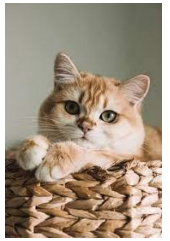
- First, we require a dataset containing of many examples of the entity we are trying to generate (e.g., image of cats)
- This is known as the training data, and one data point is called an **observation**

Training

Generative Model

- A generative model describes how a dataset is generated, in terms of a probabilistic model
- **By sampling from this model, we are able to generate new data** (e.g. new photo of a cat)

Generation/ Sampling



Source: https://samim.io; MacKinsey & Company, What is generative AI?

Generative AI Revolution – examples

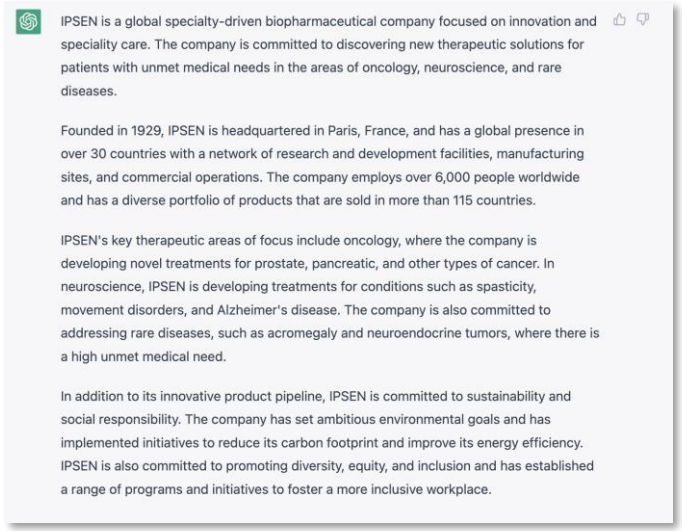
Ask — **Generative Model** — **New data**

Generation

« Can you give me a description of the IPSEN company?»

ChatGPT

Generation



IPSEN is a global specialty-driven biopharmaceutical company focused on innovation and speciality care. The company is committed to discovering new therapeutic solutions for patients with unmet medical needs in the areas of oncology, neuroscience, and rare diseases.

Founded in 1929, IPSEN is headquartered in Paris, France, and has a global presence in over 30 countries with a network of research and development facilities, manufacturing sites, and commercial operations. The company employs over 6,000 people worldwide and has a diverse portfolio of products that are sold in more than 115 countries.

IPSEN's key therapeutic areas of focus include oncology, where the company is developing novel treatments for prostate, pancreatic, and other types of cancer. In neuroscience, IPSEN is developing treatments for conditions such as spasticity, movement disorders, and Alzheimer's disease. The company is also committed to addressing rare diseases, such as acromegaly and neuroendocrine tumors, where there is a high unmet medical need.

In addition to its innovative product pipeline, IPSEN is committed to sustainability and social responsibility. The company has set ambitious environmental goals and has implemented initiatives to reduce its carbon footprint and improve its energy efficiency. IPSEN is also committed to promoting diversity, equity, and inclusion and has established a range of programs and initiatives to foster a more inclusive workplace.

- You may be familiar with ChatGPT, a type of generative AI designed to produce written text.
- You have the possibility to engage with it at https://chat.openai.com/

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Generative AI Revolution – Typical tools

Text

co:here

Meta

ChatGPT

Bard

Stanford Alpaca

ANTHROP\C

DeepL

Health

AQEMIA

VERISIMLife

MELLODDY

Benevolent AI

Insilico Medicine

Image/video

Midjourney

OPUS

craiyon

runway

stability.ai

Code

replit

GitHub Copilot

tabnine

aws CodeWhisperer

mutable.ai

Speech/Music

Eleven Labs

coqui

SOUNDRAW

WELLSAID

Generative AI Revolution – potential use cases

Illustrative – non exhaustive

Synthetic patient data	▪ Generative AI can create synthetic datasets that mimic real-word patient data, protecting patient privacy while improving the scale of training data
Biomedical NLP[1] / EHR[2] document	▪ Biomedical NLP refers to automated methods to manipulate human language in the biomedical domain, ranging from natural language understanding to natural language generation tasks ▪ Generative AI can ingest biomedical literature at scale and extract, summarize, and analyze relevant information to **support clinical decision-making** ▪ Leveraging generative AI to extract data from Real World Data and EHR documents
Search engine with summaries	▪ AI-powered Q&A engine could be used to synthetize and analyze primary market research findings or scientific publications outputs, especially when the sample size is extensive

Note: [1]natural language processing; [2]electronic health record

Sources: Cbinsingths; MIT News, AI system can generate novel proteins that meet structure design targets, 2023; IQVIA, Generative AI in Life Sciences: Evaluating LLMs/GPT for summarization of Primary Market Research, 2023

Generative AI Revolution – potential use cases

Illustrative – non exhaustive

Drug design	▪ Pharma companies can use generative AI in combination with traditional chemistry models to **predict molecular structures**, bringing protein and drug discovery timelines down drastically
Suggestion of new protein targets	▪ Added to bioinformatics understanding (e.g., biomolecular thermodynamics, interactions), generative AI system can generate target proteins from existing proteins in human body ▪ The generated proteins can be used to identify new targets for existing compounds
Radiology image enhancement	▪ Radiologists can lean on generative AI to reconstruct and de-noise radiology scans, lowering the need for rescans and reducing patients' exposure to radiation and heavy metals

Sources: Cbinsingths; MIT News, AI system can generate novel proteins that meet structure design targets, 2023; IQVIA, Generative AI in Life Sciences: Evaluating LLMs/GPT for summarization of Primary Market Research, 2023

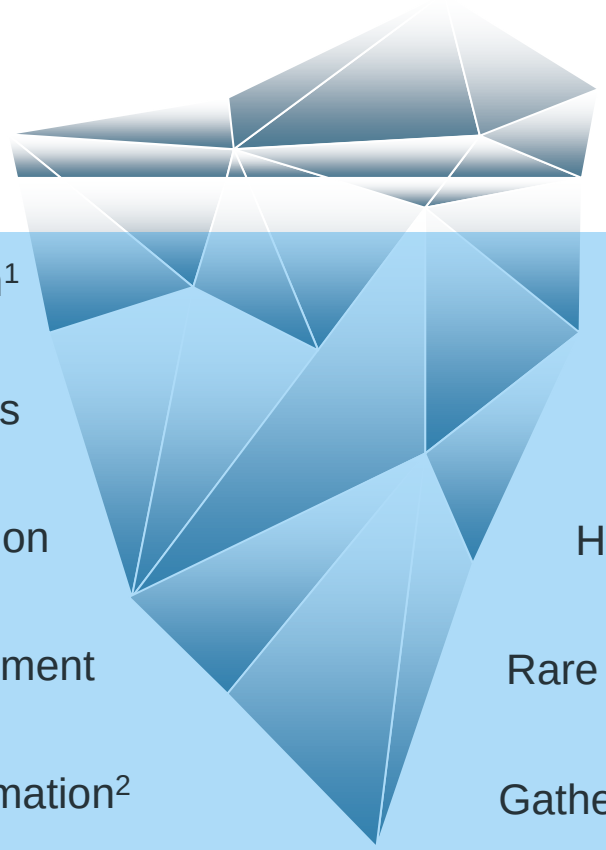
Warnings on potential drawbacks and risks before deploying generative solutions

Human like content generation

Boost human productivity

Open the door to new applications

Sometimes



False and misleading information[1]

Biases

Propaganda and deception

Copyright infringement

Private information[2]

Impact on the labour market[3]

Tons of carbon emissions[4]

Huge quantities of energy/water

Rare metals for manufacturing hardware

Gather your data to improve models

[1]Identification of false Guardian articles made up by ChatGPT (www.theguardian.com/commentisfree/2023/apr/06/ai-chatgpt-guardian-technology-risks-fake-article); [2]Samsung banned ChatGPT and other AI-powered chatbotsuse among its employees after sensitive information leak (Samsung Bans ChatGPT Among Employees After Sensitive Code Leak (forbes.com)); [3]According to the World Economic Forum, by 2025, AI is expected to automate 75m jobs globally, while creating 133m new jobs in their place (www.weforum.org/press/2018/09/machines-will-do-more-tasks-than-humans-by-2025-but-robot-revolution-will-still-create-58-million-net-new-jobs-in-next-five-years/); [4]As reported by the MIT Technology Review, training a single AI model can emit 626,000+ pounds of CO2 equivalent, which is 5x the lifetime carbon emissions of an average passenger car (https://carboncredits.com/how-big-is-the-co2-footprint-of-ai-models-chatgpts-emissions/)

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04 Key considerations working with AI

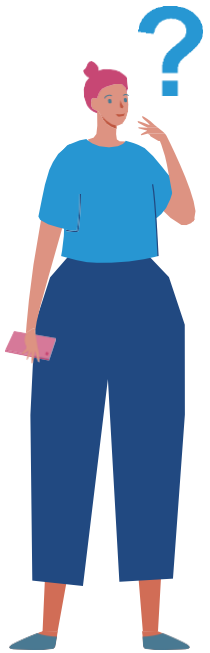
Guiding principles when considering AI solutions

We positively embrace change and see AI as an opportunity for enhanced innovation. We are committed to being part of the AI journey.

We recognize that the pace of change is considerable and likely to increase. Therefore, we remain committed to staying up to date.

We recognize that AI may introduce new risks to how we work. However, existing obligations related to confidentiality, privacy, security and business ethics continue to apply in the use of AI.

Some key considerations to follow when working with AI



Questions about the machine learning model

Question the data used to train the machine learning model

- Is it representative of my real-world situation?
- Is it respecting confidentiality, copyright and data privacy laws during sourcing and use?

Question the explainability of the machine Learning model

- Will we be able to explain the outcome/ prediction in human terms and why the inner mechanics impact the prediction vs. “black box” algorithms (Model explainability should be a driver of development as regulatory agencies will not accept outcomes from “black box” algorithms)
- Will we be able to assess the reliability of the outcome?

Questions about the usage of the AI tool

Question the input data provided to the model

- To what extent I am allowed to source and use the data for this specific use case? Am I taking into consideration the risk associated? (e.g., protecting Ipsen confidential information, personal data and data privacy obligations and security and ethics and compliance policies)
- Where my input data will be stored to be processed?

Question the model output

- How do we ensure there is no discrimination or lack of ethics that may influence model’s outputs?
- How do we prevent the AI from generating inappropriate, harmful, or illegal content?
- How do we ensure confidential Ipsen information is not being disclosed?

Get the support of **key experts with specific skillsets** (e.g., data science, data engineering, digital) to assess above key considerations

Reminders: Warnings before deploying such solutions

Do not use data from generated content without verification

- Models can hallucinate and generate fake data
- Always use content from associated sources
- Remain accountable of decision you make based on these data

Do not upload sensitive information on open generative models

- Free access models can store and use the data submitted
- Do not provide to AI tool any data that is protected by IP and/or covered by confidentiality
- Data privacy needs to be clarified before any upload or prompting

Pay attention to server location

- Legislation differs depending on countries
- We need to know where the computation is run to ensure compliance
- Security of company systems needs to be maintained

All current Ipsen policies **still apply** to projects including use of AI
(governance and compliance policies such as cybersecurity, data privacy, contract policies)

Reminders: AI Ethics principles

- **Empowering humans**: Individuals impacted by AI should always be allowed to control the use of their personal information.
- **Human control**: AI should not be given complete autonomy in decision making, machine autonomy must be restricted and made intrinsically reversible. Freedom of choice of end users should always be considered and respected.
- **Privacy, security and safety by design:** Data protection regulation, technical limitations on data re-use, security and privacy preserving measures (pseudonymization, anonymization, encryption).
- **Accountability**: Pharma companies have proper governance, risk management system, regular monitoring of AI systems in place.
- **Fairness and minimization of bias**: Seek to minimize bias and maximize fairness. Continuous monitoring and understanding to adapt AI systems to correct for bias in all AI lifecycle.
- **Transparency, explainability and ethical use**: Publicly describe when and how AI initiatives are used, its goals, assumptions that power an AI system, its limitations.
- **Human well-being, human safety and the public interest**: AI technologies should not harm people. Monitoring and measures should be in place to ensure that AI technologies work as designed and to assess whether they have any detrimental impact on individual patients or groups. Appropriate safeguards should be in place to protect individuals from stigmatization or discrimination due to their health status.
- **Responsiveness and sustainability**: When an AI technology is ineffective or engenders dissatisfaction, the duty to be responsive requires a process to resolve the problem, which may include terminating use of the technology. Use of AI must be consistent with society's efforts to reduce the impact of human beings on the earth's environment, ecosystems and climate.

References: IFPMA Artificial Intelligence Principles – IFPMA
Ethics and governance of artificial intelligence for health (who.int)

Reminders: Key actions on GDPR compliance*

(where personal data is used)

1. Undertake a Data Protection Impact Assessment (DPIA), before finalizing the design of the project.

2. Establish the roles of Ipsen and Suppliers – "data controllers/processors" and put appropriate contract terms in place.

3. Ensure that there is a legal basis for using the personal data in this way – and an extra condition for using any special category data.

4. Ensure that all individuals have been fully informed of the use of AI with an appropriate Privacy Notice.

5. If automated decisions made by AI have a significant effect on individuals certain rules apply, including obtaining consent in some cases and putting in place a method for human review.

Key privacy considerations

1. Minimise the data used in AI, wherever possible.
2. Ensure that any anonymous data is truly anonymous. Where data is pseudonymised, e.g. just the names and ID removed, it still counts as personal data.
3. Understand what happens with the data in supplier AI systems.
4. How has the supplier assured that any decisions or outcomes from the AI are free from bias and are fair?
5. Is there a way to handle individuals' rights to access, erase or update their data?
6. Know where data is processed to take account of any international transfer restrictions.

*Get support **from your local legal contacts for how to comply with local privacy laws.**


WHAT WILL BE THE IMPACT OF CHATGPT ON OUR BUSINESS?
THERE'S A LOT WE DON'T KNOW FOR SURE...
LIKE HOW MUCH OF WHAT IT SAYS IS MADE UP...
OR IF IT WILL TAKE AWAY OUR JOBS...
OR THE SECURITY RISKS...
OR IF IT COULD DAMAGE OUR REPUTATION...
WHAT DO WE KNOW FOR SURE?
ONLY THAT WE WANT TO ADOPT IT EVERYWHERE AS FAST AS WE CAN.
TOM FISH BURNE
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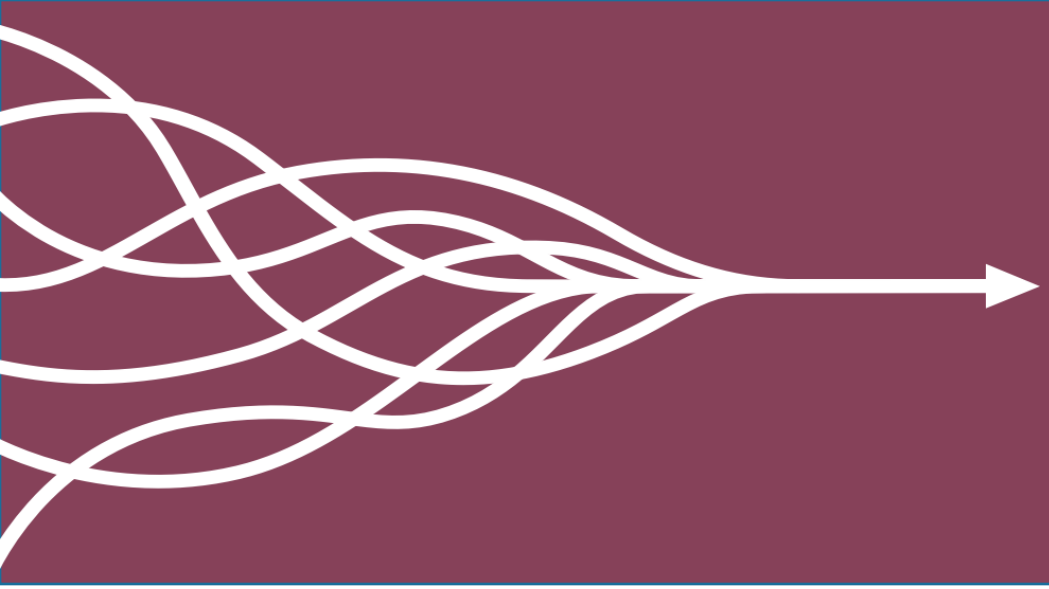


05 Points of contact

Points of contact

AI and Digital Factory team

Yoann
Head of Global AI & Digital factory

Boris
Lead Data Scientist

Vincent
Web & Digital Delivery Lead

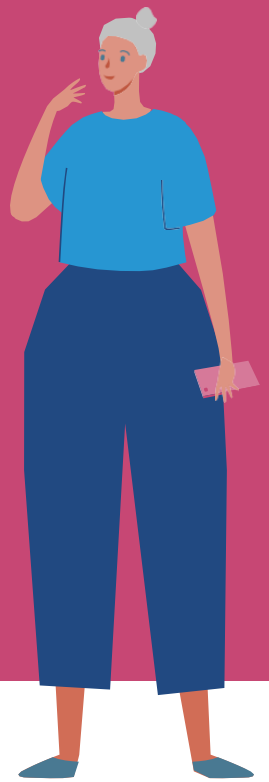
working in collaboration with…

- **Business Ethics**
- **Legal**
- **Procurement**
- **Data value office**
- **IT**
- **Data Privacy Officer**

Before exploring AI opportunities, it is important to ask **whether AI is really the solution to a given problem and how project success will be measured**

Reach out to your **functional transformation lead** or **Lauren Li and/ or David Elvira**

Thank you



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Will be further enriched with company use cases

06 Appendix

Deep dive in use cases (1/4)

Illustrative – non exhaustive

Research and early development

Use cases output	How
Drug target identification, selection and prioritization	• From existing compounds, we can train models to generate protein sequences using large language models. Such models could be used to identify proteins within the human body for which an existing IPSEN drug could bind to a target.
In silico compound screening and design for small molecules	• In a similar manner as above, large language models can be trained to generate new compounds from already identified drug-molecule interactions. Doing so, we can identify new compounds that can bind to a target identified by the company. The universe of possible compounds being 10^60, it is critical to narrow down the possible compounds using such methods.
Identify new biomarkers from images, genomics, RWD & smart devices	• Machine learning methods can be used to look at large amounts of data. If we take the example of RWD, we can use ML to identify what metrics from blood sample lead to higher risk of Follicular Lymphoma on top of existing biomarkers.
Dose/dosing regimen optimization	• Knowing compound solubility helps understanding the pharmacokinetics of a compound and its dosing impact. Regression models in machine learning help predicting the solubility of a compound from its molecule sequence.

Deep dive in use cases (2/4)

Illustrative – non exhaustive

Development, regulatory and safety

Use cases output	How
Selection of trial participants	• Depending on cancer mutations, cancer progression can vary. Looking at RWD, genomics or lab results we can better anticipate disease progression for each patient initially selected for a clinical trials. Doing so, we diminish the number of participants and focus on the patients whose disease progression matches the trial goal.
Trial data collection, management & analysis	• Trial data can be collected and stored over time while quality is monitored continuously. As data is centralized it opens the door to clinical trials modelling such as in silico trial models.
Adherence/persistence monitoring	• Persistence in clinical trials is usually higher than in real life. Models that use disease type and patient medical history can be created to better predict real world treatment duration from clinical trials data using RWD and previous clinical trials outcomes.
Clinical endpoints assessment	• Trials features and characteristics from IPSEN trial history can be extracted. During ongoing trials we can look at the new data with the knowledge of previous trials. Using the combination of data, we can use models that helps anticipating trials outcomes. Such anticipation can lead to trial early stopping if the results are not promising.
Active safety surveillance, AEs reporting classification	• AEs reported as text can be screened using deep learning models. Reports can be labelled or classified depending on their content to ease out future AE management and sorting.

Deep dive in use cases (3/4)

Illustrative – non exhaustive

Manufacturing and supply chain

Use cases output	How
Quality exception monitoring	• Data of historical batches can be stored and accessible. Machine learning models can be trained on those historical data to track exceptions of new batches. Anomaly of ongoing batches can be detected in a multivariate manner instead of classical deviation and batches in production can be stopped earlier if the predicted outcome does not meet regulatory standards.
Smart monitoring and maintenance	• Vision computing methods can be used to continuously monitor the production line. Vials positioning can be checked and warnings triggered if tilted vials are identified. For historical equipment, production data can be gathered and the pattern before equipment failure can be identified to run maintenance before failure.
End-to-end supply chain planning	• As demand in drugs can be predicted accurately, manufacturing sites can prevent shortages in supplies while diminishing storage costs.

Deep dive in use cases (4/4)

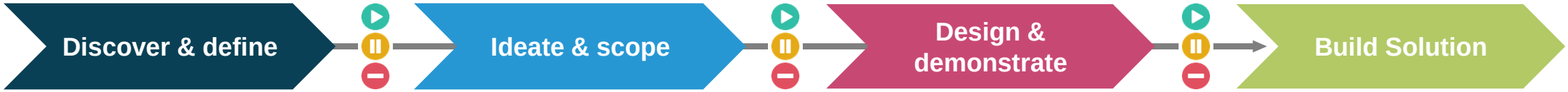
Illustrative – non exhaustive

Commercial & Medical Affairs

Use cases output	How
Improve patient and customer journey	• Content is crucial in the customer journey. AI can help in labelling the content associated to emails or calls to consolidate the database of actions with content information. Once consolidated, it can be used to provide suggestion in the journey for marketing teams.
Commercial spend optimization	• Looking at historical data related to marketing actions, field force actions and sales actions, we can build the link between the actions that were taken and their impact on sales using causal inference models. Those models provide insights on which actions were impactful in sales to rationalize rep actions strategy and optimize the type and number of actions taken.
Field force effectiveness (e.g. next best actions)	• Using social media listening or looking at publications, we can better understand the topics of interest of an HCP. As we understand the content that can be impactful, suggestions can be provided by looking at the previous actions to plan the next best action.
Understanding/optimizing RWD to identify patients, define targeting approaches etc.	• Using RWD in the US, we can identify patients that can benefit from IPSEN therapies using their medical history. Those patients can be linked to a reference HCP, thus providing recommendation to field forces on which HCP to contact.

Typical workflow

How to formalize an AI project



A team within IPSEN identifies a pain point or development opportunity that can be addressed with AI.

The ideal solution is pictured in the big lines to assess a first round of feasibility.

If general feasibility is approved, the design of the product is refined. First critical features can be extracted and prioritized.

The project can also be scoped in terms of timelines, cost and added value.

When the product scope and features are validated, a proof of concept can be developed (PoC).

This PoC will help identifying pain points in the development and reevaluate the timelines and costs. I will also help in refining the features and user flow.

Once the features, timelines, costs and objectives are clear, the development of a platform directed to the user can be launched.

Along this process, continuous feedback from the end user is required to fine the direction of the technical team.

Go/No Go after each phase

Use case example: Discover & define

Enable users to ask questions regarding an SOP

Discover & define

1. **SOURCE AN INITATIVE**
2. **UNDERSTAND FINAL USERS & MARKET**
3. **ASSESS FEASIBILITY**

1.
- A team within IPSEN identified the need to search within an SOP (Standard Operating Procedure). The data product would enable users to ask questions regarding the SOP and obtain references within the specific SOP associated to the question and a summary of the answer from the references

2.
- The end users would be people within IPSEN that want to follow the SOP guidelines as they are working on a manuscript

3.
- To obtain a first view of the feasibility of the product, the Ipsen team contact the AI & Digital Factory team

Use case example: Ideate & scope

Enable users to ask questions regarding an SOP

Ideate & scope

1 GENERATE SOLUTIONS

2 QUALIFY SOLUTIONS

Data & tech Assessment:
- *Data sources*
- *Data models*
- *Tech solutions*

Data & AI risks

Identify partners (intern/vendors)

3 PREPARE PROJECT ORGANIZATION

Tech KPIs

Detailed Bcase

1

Competitive landscape on AI approaches, looking at vendor solutions, open source & research

- Scope the users needs:
  - Interaction in natural language
  - Quickly find elements of interest in the SOP
  - Summarize information

2

Data sources need to be identified (list of SOPs to look at)

- What is the format of the data? Is it only text? Are there graphs?
- If we are going through an external vendor, how are they going to use our data?
- Is the API private?
- Do we decide to build the solution internally or ask the help of an external vendor?

3

- List the KPIs that will define the success of the project:
  - Quality of the summary answers generated by the model
  - Quality of the references provided

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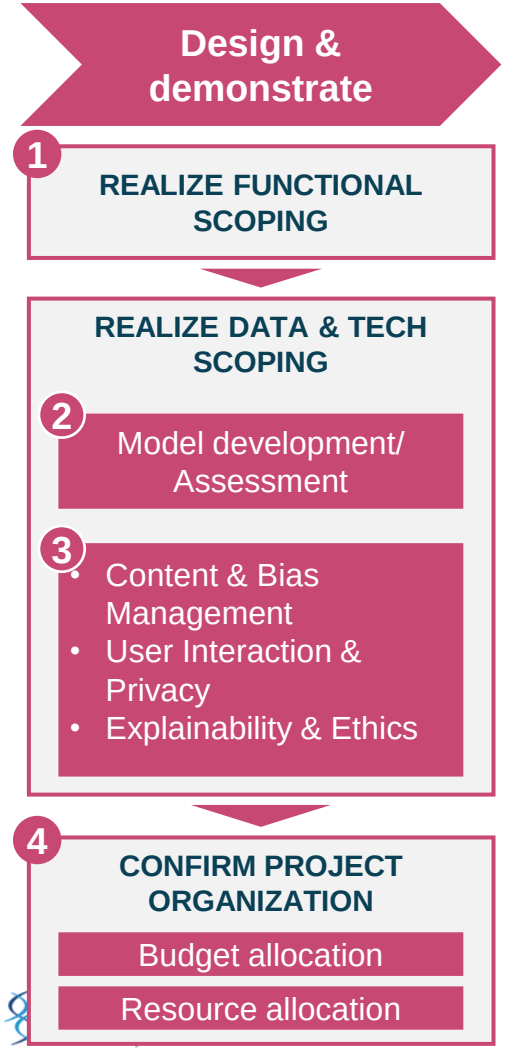
Use case example: Design & demonstrate

Enable users to ask questions regarding an SOP



1. Define the flow of the solution and the list of features that will need to be implemented as a proof of concept:
   - As a user I want to search within an SOP by asking a question in natural language
   - As a user I want to obtain a paragraph of maximum 10 sentences to answer my question
   - As a user I want to check the accuracy by having access to the references used build the answer to my question

2. What is the training strategy?: Train on previous SOPs, different SOP types, etc.
   - How the solution is evaluated ?: metrics, samples of human verified Q/A on SOPs, test on non-SOP documents, non-SOP related questions, etc.

3. Along the process, ensure that models content and biases are continuously checked
   - Biases can be induced by lack of representation of certain data points, human stereotypes that will be found in the training dataset can also lead to biases in the model.
     - Are the subgroups identifiable (different types of SOPs)?
     - Have you assessed fairness/bias introduced by the training (e.g., too specific for certain SOPs)?
     - Ideally, the developers of the model should provide insights to the users on the reasoning of the model. What are the important features guiding the output? How to question the model?

4. Technical challenges are usually discovered during the design & demonstrate phase. It will be important to consider the new information to adjust the budget and redefine the resources needed to build the end product

Use case example: Build solution

Enable users to ask questions regarding an SOP

Build Solution

1

DEVELOP Solution

- Development
- Value monitoring
- Real World Test

2

SCALE & RUN SOLUTION

- Monitor Model Behavior
- Third-Party Audit: Red Teaming
- Maintenance & User support

1

- When the proof of concept has been validated, the first usable application can be developed
- Along this process, continuous feedback from the customer is required to ensure appropriate development process
- Frequent testing and review sessions will help this process:
  - Was the model tested on real world data? How does the model handle outlier questions?
  - Does the model generate inappropriate answers or harmful content?
  - What is the global user feeling on the output quality?

2

- When users are satisfied, the solution can be scaled and go for run
- Few parameters need to be checked:
  - Is there drift in the data to predict? (e.g., different SOP format, type)
  - Does the model need retraining?
  - How much does it cost to run the product?