Inserm

FRANCE MÉDECINE GÉNOMIQUE 2025
aviesan

Memorandum of understanding for the Danish-French partnership in advancement of precision medicine

The Danish National Genome Center, DGNC, represented by its CEO Bettina Lundgren,

and

The Institut National de la Santé et de la Recherche Médicale (Inserm), with registered office in Paris (France) represented by its Chairman and CEO, Didier Samuel, acting in the name and on behalf of the members of the French National Alliance for Life Sciences and Health,

hereinafter referred to as 'Aviesan', jointly referred to as 'the Parties'.

CONSIDERING

- That Danish National Genome Center (DNGC) is an agency under the Ministry of Health, supporting the development of personalised medicine in collaboration with the Danish healthcare system, research institutions, and patient organisations. The DNGC develops and runs a joint, national infrastructure for personalised medicine, including a national infrastructure for performing genome sequencing and storage of information in a national genome database, and a national research infrastructure supporting the further development of personalised medicine.
- That Aviesan, the French National Alliance for Life Sciences and Health, is the umbrella organisation in France which notably leads and delivers the 2025 French Genomic Medicine Initiative (PFMG 2025), a national initiative which aims to position France as a leading country in the area of personalised and precision medicine, to prepare for the integration of genomic medicine into the healthcare pathway and to establish a national genomic medicine framework capable of driving scientific and technological innovation;
- That France and Denmark share the ambition of building and operating advanced and competitive genomic healthcare and research ecosystems within personalised/precision medicine. They have similar and complementary objectives, representing two large public commitments, to create infrastructures delivering a global leading 21st Century personalised/precision medicine service. This common vision for personalised/precision medicine, and in specific genomics and our shared national attributes, makes it feasible to consider how a partnership between PFMG 2025 and DNGC could accelerate personalised/precision medicine.
- That as part of this strategic alliance, the Parties will share experience, and exchange knowledge on implementation of genomics and precision medicine in healthcare and mutually demonstrate the clinical utility of genomic medicine.
- That both Parties recognise that a collaboration is of mutual benefit and wish to further strengthen the scientific and organizational collaboration between the Parties. Together, the Parties can more comprehensively address specific outstanding academic research, data analysis and bioinformatic questions of outmost importance in genomics and precision medicine and form a partnership presenting opportunities for synergy from the existing critical mass of talent in both nations.

SCOPE OF COOPERATION

The Parties have identified a significant mutual benefit of collaboration with the aim to advance genomics and precision medicine on a strategic, structural, and content-specific level.

This strategic alliance will promote faster and more successful advances by building common approaches for implementation of genomic medicine/precision medicine in healthcare. The Parties agree on the following areas of collaboration, constituting this Memorandum of Understanding ("MoU").

ARTICLE 1: COLLABORATIVE ACTIVITIES

The main collaborative activities promoted under this MoU concern:

1. Clinical output of Whole Genome Sequencing
   1.1 Indications for clinical outcomes for different patient groups
2. Legal and economic framework
   2.1 Exchange experience on methods and models for measuring economic impact of Whole Genome Sequencing
   2.2 Exchange experience on legal obstacles (GDPR, clinical data used for research and research data used in the clinic)

3. Tools, quality and interpretation
   3.1 Exchange experience on standardization, quality assurance and validation of assays for precision diagnostics, including bioinformatic analyses/pipelines
   3.2 Exchange experience and expertise on data protection & ethical issues, related to the use of genome sequencing, in order to remain GDPR-compliant
   3.3 Exchange experience on what tools are offered to personnel in the healthcare sector and researchers to support high-quality personalised medicine as standard-of-care and research.

4. Storage and re-processing
   4.1 Exchange experience and expertise on development of national informatics platforms for secure storage and sharing of data
   4.2 Exchange experience on re-processing of data including:
   4.2.1 How to annotate variants and primary sequence
   4.2.2 How to store variants and raw data
   4.2.3 How to measure the clinical value of re-processing

5. Communication to patients and citizens
   5.1 Exchange experience on creating material to support conversations between healthcare professionals and patients, and foster informed consent.
   5.2 Exchange experience on designing and conducting citizen surveys.
   5.3 Exchange experience on communicating to a broader public.
   5.4 Exchange experience on the use of digital consent.
   5.5 Exchange experience on involving patients/citizens actively in the development of personalised medicine and national data infrastructures.

ARTICLE 2: PRINCIPLES

The principles promoted under this MoU are:

1. Formation of joint Aviesan and DNGC working group(s) with identified leaders from Aviesan and DNGC. The role of the working group/s will be to determine the scope of the collaboration, develop a roadmap and deliverables, ensuring that channels of communication are created and remain active.
2. The exchange of knowledge and experience between Aviesan and DNGC.
3. Organization of joint events and activities for the purpose of promoting transnational collaboration and creating links between genomics specialists of both Parties.

4. The fields in which the Parties will collaborate are based on mutual interest, as agreed in writing from time to time.
5. Research involving both Parties which results in processing of personal data will be regulated separately.
6. Each Party will bear the costs relating to its contribution in the collaborative activities.
7. The implementation of this MoU will be subject to specific agreements mutually discussed and agreed upon in writing by authorized representatives of both Parties prior to the initiation of the activity. These specific agreements shall include but not be limited to, intellectual property rights, confidentiality, liability, publication, communication, finance and other appropriate matters for implementation of the cooperative activities under this MoU. The specific agreements must always comply with both international and national law.

ARTICLE 3: CONFIDENTIALITY AND USE OF NAME

Each Party undertakes not to transfer knowledge or information belonging to the other Party to which the said Party has had access in the context of this MoU to third parties without the written consent of the other Party.

This commitment, however, does not apply to information that:

a) has ever been in the public domain by the time of its communication or subsequently entered the public domain without fault or negligence on the Party which has received the information;
b) has been communicated to the Parties by a third party without any restriction in respect to their confidentiality;
c) the other Party already owned before its communication;
d) has been discovered or independently developed by one of the Parties without use of the information held by the other Party;
e) the law requires to be disclosed.

Neither Party will use the name or logo of the other Parties in advertising pieces, press releases, advertisements or any other promotional material that involves the subject of this MoU without the written approval of the Party concerned. This article remains valid even after the termination or expiration of the duration of the MoU for a period of five (5) years.

ARTICLE 4: QUESTIONS AND CONSULTATION

In the event that questions should arise concerning the interpretation of the provisions of the MoU, or problems should be caused by matters not prescribed herein, both Parties will consult with each other and conclude on a mutually acceptable solution.

ARTICLE 5: DURATION AND AMENDMENT

1. This MoU will come into effect upon signature by both Parties and remain valid until march 5th 2026 with the possibility of prolongation for a period of three years thereafter,

unless either Party chooses to terminate it sooner having first given six (6) months written notice of this intention to the other Party.

2. This MoU may be amended or renewed by the mutual written agreement of both Parties.

Drawn up in two original copies in English language, both having the same equal validity.

Signature

Aviesan:

6/3/2023
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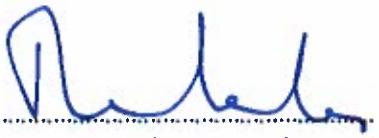
(Place, date)



Thomas Lombès Vice CEO for strategy, by delegation of signature of Didier Samuel Chairman & CEO Inserm, President Aviesan

Danish National Genome Center:

6/3-23
.....
(Place, date)

Bettina Lundgren, CEO Danish National Genome Center