



**DEVELOPING AN INTERNATIONAL CONSORTIUM
TO DEVELOP AN IMPLANTABLE ARTIFICIAL KIDNEY**

Meeting notes from August 19, 2019 6AM – 7AM alongside IDEAS meeting
Graduate Hotel, Ketcham Room, Seattle, Washington

ATTENDEES (list with names, photos and contact details will be distributed):

Murray Sheldon	Stephen Ash	Susan Allison
Prabir Roy-Chaudhury	Dean Kamen	Glenda Roberts
Jonathan Himmelfarb	Bruce Culleton	Nieltje Gedney
Buddy Ratner	Ishihara Kazuhiko	Daniel Gossett
Sandeep Patel	Allison Tong	Nichole Jefferson
Benjamin Fisher	Melissa West	plus 2 extra guests
Fokko Wieringa	Tom Oostrom	

PURPOSE:

Current treatment for people with End-Stage Renal Disease (ESRD) is either dialysis [hemo, peritoneal, intermittent (in-center, at home or elsewhere), continuous] or a kidney transplant [living donor or deceased donor]. None of these treatments are ideal, they are all expensive and, as for present dialysis, people suffer from poor quality of life and a significantly shortened life span. Based on the state of technology development, it seems possible that an artificial kidney capable of most basic filtration and cellular functions can stepwise be developed within a timeframe of 5-10 years as described in the Kidney Health Initiative Technology Roadmap for Innovative Approaches to Renal Replacement Therapy (Oct 2018). Additionally, it appears that at least some (if not most) of the scientific expertise and technological skills needed to do this, lie scattered around the world. As ESRD is a world-wide problem, this Consortium is being developed to engage the interest of a diverse group of scientists, engineers, physicians, patients and other stakeholders to work together to develop an implantable bioengineered kidney for the benefit of humanity. The Consortium will be agnostic to the exact form of resulting product(s), (whether a technical device coupled with a cellular bioreactor, a xenotransplantable organ, a chimera or other regenerated form). Goal is that targeted solution(s) will enable people with ESRD to obtain a product that substantially improves the quality & length of their lives, which will be affordable and become available throughout the world.

The recently published International Society of Nephrology Kidney Health Atlas (2019) found that “by 2030, 14.5 million people around the world will have end-stage kidney disease (ESKD), yet only 5.4 million will be treated due to economic, social and political factors. Additionally, more than 2 million people will die each year due to little or no access to hemodialysis or kidney transplantation.” It is incumbent upon **us** now – as world-class experts in kidney diseases, technology development and innovation – to complete the work recently begun by groups such as the KHI Roadmap team and the ISN Global Kidney Health developers and create an alternative to dialysis in its current form that can become accessible to all people world-wide as a humanitarian effort for health and peace. If not us, then who? If not now, then when? All countries face this problem! Preferred approach is that milestones along the way will benefit patients as soon as possible (just as e.g. years before the first moon landing telecommunication satellites already brought benefit, although just being milestones along the road).



Given the short notice, we know that not all world-class experts can make it to this meeting. Hence, this is a reconnaissance meeting where no formal voting or the like will take place. We simply target an open and constructive atmosphere to discuss how to build a functional world-wide consortium.

AGENDA

NOTE: All speakers were instructed to be very brief to fit it all in just one hour.

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| 6:00AM – 6:10AM | Vision for the Consortium: Murray Sheldon (FDA/KHI)
No Slides, see previous text on purpose. |
| 6:10AM – 6:15AM | KHI Roadmap summary: Melissa West (KHI)
The purpose and structure of the KHI innovation roadmap is explained.
Also where to download it. |
| 6:15AM – 6:20AM | KidneyX and U.S. Executive Order Update: Sandeep Patel (HHS)
Gives a briefing about the coming stages of KidneyX and government plans. |
| 6:20AM – 6:25AM | Comment from FDA: Benjamin Fisher
Summarizes the experiences that FDA gained so far and which pathways will be offered to stimulate innovation. |
| 6:25AM – 6:30AM | Technology Readiness Levels: Fokko Wieringa
Very quick intro to what a TRL-scale is, with a request to the audience to think about what the TRL of THEIR technology is, and to help compiling a dedicated TRL-scale for an Implantable Artificial Kidney. An extensive NATO report on TRL-scales for medical devices, that could serve as a starting point, will additionally be distributed. |
| 6:30AM – 6:35AM | Comment from IFAO: Stephen Ash
The structure of The International Federation for Artificial Organs (IFAO) and its' world-wide sister organizations is explained. |
| 6:35AM – 6:50AM | Comments from international participants (5 min each): <ul style="list-style-type: none">- Tom Oostrom (Netherlands)
Represented Dutch Kidney Foundation and European Kidney Health Alliance (EKHA). Their goals match with the KHI Roadmap.- Allison Tong (Australia)
Lists some ongoing projects in Australia.- Kazuhiko Ishihara (Japan)
Gives update on Biomaterials Research in Japan |
| 6:50AM – 7:00AM | Wrap up and next steps <ul style="list-style-type: none">- Short notes will be distributed, together with slide sets- Fokko and Steve will inform the “Artificial Organs” Societies (done)- The international Nephrology community will also be informed (Tom, Murray, Melissa)- A European KIDNEW meeting will be organized in 2020 (Tom, Fokko)- A survey will be compiled and send out by e-mail (Murray & Fokko with help of Marcus Schoenfeld and Elcke Vloedgraven) |

We greatly acknowledge all who attended on this exceptionally early hour of the day!