As we move toward the completion of the first quarter of 2022, the military invasion of Ukraine is a reminder that peace is never to be taken for granted. I hope for a peaceful resolution soon and look forward to continuing to work with our friends and colleagues across the world to transform healthcare and with it, the quality of life for all people. In this way, we do our part to contribute to a better world.

One of the unique features of HTAi is our interest in, and attention to, the full lifecycle associated with health technologies. This interest and attention will be on full display this year at both our Global Policy Forum (March 26-28) and the Annual Meeting (June 25-29). The GPF is deliberately taking a long view of the subject, with its theme of "HTA 2025 and beyond: lifecycle approaches to promote engagement and efficiency in health technology assessment". The Annual Meeting is examining the conditions that need to be met to make a true lifecycle approach a reality.

Calls for a lifecycle approach to determine the value of medicines, devices and other health technologies have grown rapidly in recent years. This is particularly true as we strive for patient-centric health systems. To get there, it is important to explore the value of health technologies from an early stage of development through their maturation and (potential) decline as new developments render the technology obsolete.

For the health technology assessment (HTA) community to meaningfully participate in a rapidly evolving global health ecosystem that considers value across the lifecycle, several questions must be addressed. These include:

- What are the implications for the position and role of HTA in healthcare decision-making at a global level and the potential for HTA bodies to participate across the whole lifecycle of health technologies?
- How does a lifecycle approach to HTA contribute to legitimacy, relevance, and public confidence in healthcare decision-making?
- What are the implications of taking a lifecycle approach for setting HTA priorities and ensuring sustainability of the HTA process?
- How can unmet medical needs influence HTA priority setting, and which elements of unmet medical need should be considered?
- What does effective and efficient integration of multiple stakeholder perspectives look like in a lifecycle approach?

These questions, and others, will animate HTAi's Global Policy Forum and Annual Meeting in 2022. I look forward to welcoming GPF members to Vancouver, Canada, in March and the HTAi membership to Utrecht in June. While there will be provision for virtual participation in both events, it is a great pleasure to return to some form of in-person dialogue with these events.

In gratitude for your continued support of our Society.

Rob Abbott
Executive Director

2022 Board Nominations

The call for nominations has now closed. We thank everyone who helped spread the word and especially those who have the desire and courage to put their names forward to stand for elections and serve the Society.

Next Steps

On April 6, the Society's members in good standing will receive a ballot from CIVICA, a third-party electoral service, to vote for four (4) open Director positions. Once you receive your electronic ballot, you will be able to cast your vote 24 hours a day, 7 days a week, until the elections close on Friday, May 6 at 23:59 MST. Please note that the email may appear in non-primary inboxes and folders (e.g., "Spam").

More information about the 2022 Board of Directors Elections

If you have any questions regarding Board Elections, please email boardelections@htai.org.

Registration

Can you believe we're in March!?

The 2022 Annual Meeting in Utrecht, Netherlands, will be extra noteworthy: for the first time in TWO years, HTAi members and contributors will have the opportunity to meet in person once again!

If you would like to participate (in-person or virtual) and haven't registered yet, jump to it now! Early Bird registration rates are only available until Tuesday, March 24 at 11:59 p.m. MST.

Secure your seat here=

Register here

Schedule at a Glance

The 2022 Schedule at a Glance is now posted on our website! We are excited about the opportunity to see each other in person again and to continue offering a vibrant, rich program to enable meeting with our global members.

View the Schedule at a Glance

Workshops

Workshops are scheduled for June 25 - 26, with half and full-day options on both days. Half-day workshops are 3 hours, and full-day workshops are 6 hours, running from 08:00 -15:00 or 17:00 – 00:00 (UTC). With a range of exciting topics available, there is sure to be something to spark your interest from beginner to advanced. Check out the workshop descriptions and schedule and register here.

Hotel Reservations

For best availability and to receive immediate confirmation, please make your reservation online on our official booking site.

Book your hotel here

Why Stay at one of our Recommended Hotels?

Staying "within the block" is not only a convenient way to stay close and connected with activities and networking opportunities during the meeting, but it also helps keep reduce your meeting costs. HTAi has arranged special rates on behalf of our members at hotels within walking distance to the Annual Meeting Venue, Jaarbeurs.

Speaker Announcements

The list of confirmed speakers is growing each day and we will be announcing them over our social media channels in the coming weeks. Keep an eye on our website to see whose voice will join the debate and conversations at the HTAi 2022 Annual Meeting.

PCIG Pass

Did you miss the HTAi Participation Grants for Annual Meeting 2022 Utrecht?

Patients, patient representatives and caregivers this is an opportunity to join the HTAi Annual Meeting (online or in-person). It's where the world comes together to discuss and improve health technology assessment (the process that sits behind decisions about what health providers fund in more than 30 countries). This year's theme is lifecycle health technology assessment, and we're also talking about public confidence.

You told us last year that it could be hard sometimes to organize letters of support. We listened. This year, we ask for someone we can contact as a reference. This helps our global team of volunteer reviewers establish you meet the criteria if they don't know you.

We are grateful to Edwards Lifesciences, Janssen and Novartis for their sponsorship of these grants and commitment to patient participation in HTAi's Annual Meeting.

Don't miss this. Apply now. It's easy. Applications close on March 14.

Learn more about the 2022 Annual Meeting

Are you interested in learning more about the Annual Meeting? Do you want to review themes and timelines? Visit htai2022.org for all things Annual Meeting!

Please send your questions regarding the Annual Meeting to annualmeeting@htai.org.

2022 Global Policy Forum

Registration has opened for the 2022 Global Policy Forum (GPF), taking place at the Sutton Place Hotel March 26 – 28 in Vancouver, British Columbia, Canada. Unlike GPF meetings in the past, this meeting will begin on Saturday rather than Sunday to prevent a conflict with a European meeting several members are involved in. This in-person meeting will also integrate virtual features to allow for remote participation.

We are looking forward to seeing GPF members face-to-face for the first time in 2 years!

This topic for this year's Forum is "HTA 2025 and Beyond: Lifecycle Approaches to Promote Engagement and efficiency in Health Technology Assessment."

Call for not-for-profit expressions of interest.

A big thank you to the organizations who submitted Expressions of Interest to join the Global Policy Forum. After carefully reviewing the submissions, the Global Policy Forum Organizing Committee welcomed Agenzia Nazionale per i Servizi Sanitari Regionali (AGENAS) to the Forum. We are sure that AGENAS will make an important contribution to the work of the Forum, and we are looking forward to working with them in the future.

If you would like more information about the Policy Forums, please contact the Policy Forum team at policyforum@htai.org or Ali Powers, Manager, Policy Forums and Events, at apowers@htai.org.

HTAi Webinar Series

HTAi offers a live stream webinar series broadcast to all HTAi members and prospective members! Keep an eye on your inboxes and our social media channels for upcoming webinars.

Past Webinars are Available Year-Round

Have you missed any of our recent webinars? If you are interested in watching on your own schedule, you can access HTAi's impactful sessions and webcasts, which can all be found on our official YouTube channel.

Check out our latest webinar, "Evidence-Based Searching for Health Technology Assessment: Keeping up to Date with SuRe Info," presented HTAi's Information Retrieval Interest Group (IRG.)

Breakthrough Medical Devices: Work in Progress at HTAi

At the end of 2017, the Food and Drug Administration (FDA) announced its Breakthrough Devices Program, a voluntary program for medical devices and device-led combination products that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The concept behind this program consists of assisting patients in having more timely access to some specific medical devices by expediting their development, assessment, and review while preserving the Agency's regulatory standards.

But which devices can access the Program, and which characteristics must they have? Firstly, it is important to remember that the "breakthrough devices designation" applies to devices that are not yet on the US market, meaning that it must be requested before a marketing submission request such as a premarket approval application (PMA), a premarket notification (510(k)) or a request for De Novo designation.

In its guidance "Breakthrough Devices Program – Guidance for Industry and Food and Drug Administration Staff," the FDA defines two criteria that must be met to obtain such a designation. The first implies that the device *"Provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions."* To fulfil this, the applicant must provide literature or preliminary data to support the thesis that there is a reasonable expectation that the device could provide for "more effective treatment or diagnosis" relative to the current standard of care in the United States in terms of both technical (the device functions as intended) and clinical (the device could be more effective for the diagnoses/treatment of the target condition) success. Moreover, the target condition must be life-threatening (i.e., high likelihood of death if the course is not interrupted) or irreversibly debilitating (i.e., with impact on survival, day-to-day functioning, and progression to a more serious condition).

The second criterion is a set of four sub-criteria, and the device must satisfy at least one of these. Specifically, the device must *"a) Represent a breakthrough technology,"* so it must have the potential to lead to a clinical improvement, or *"b) For which no approved or cleared alternatives exist,"* so no drug, biological product, device, or combination product must have received FDA marketing authorization for the same indication, or *"c) Offers significant advantages over existing approved or cleared alternatives"* (i.e., compared to the alternatives, it has the potential to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care, or establish long-term clinical efficiencies), or *"d) Its availability is in the best interest of patients,"* so this could be seen as an umbrella criterion which

includes, for example, the case in which the device has a benefit for patients who are not tolerating or not responding to currently available therapies or addresses a public health emergency.

It goes without saying that this program's output is of high relevance to HTAi stakeholders, particularly those working in the medical devices space. The FDA does not routinely make available which devices have received the designation. The HTAi Secretariat is launching a service for members to fill this gap. It will collect information related to devices receiving the breakthrough device designation and share this with the membership. Antonio Migliore, Manager of Scientific Initiatives for HTAi, leads this effort working closely with the Medical Devices Interest Group. Watch this space for updates.

Tell a friend, share a tweet, and spread the news about HTAi! Be sure to add us to your network for up-to-date news, networking, and the latest HTA information.