

The basic concept of review of BTK devices

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COI Disclosure


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Agenda

- The basic concept of review
 - The past efforts to promote device development
 - The basic concept of review of BTK devices
 - The future efforts to promote the development of innovative devices
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The basic concept of review

Clarifying the clinical positioning of the device

- Patient population
- Treatment purpose
- Difference from conventional therapies and available products

In evaluating device efficacy...



It is important to chose clinical significant endpoints.



The past efforts to promote the development



Establishment of the guidance for the endovascular treatment devices for CLI patients ^{*1}


- Points to be considered in evaluating efficacy and safety in clinical trials.

Publication of study design concepts for the global clinical trials^{*2}

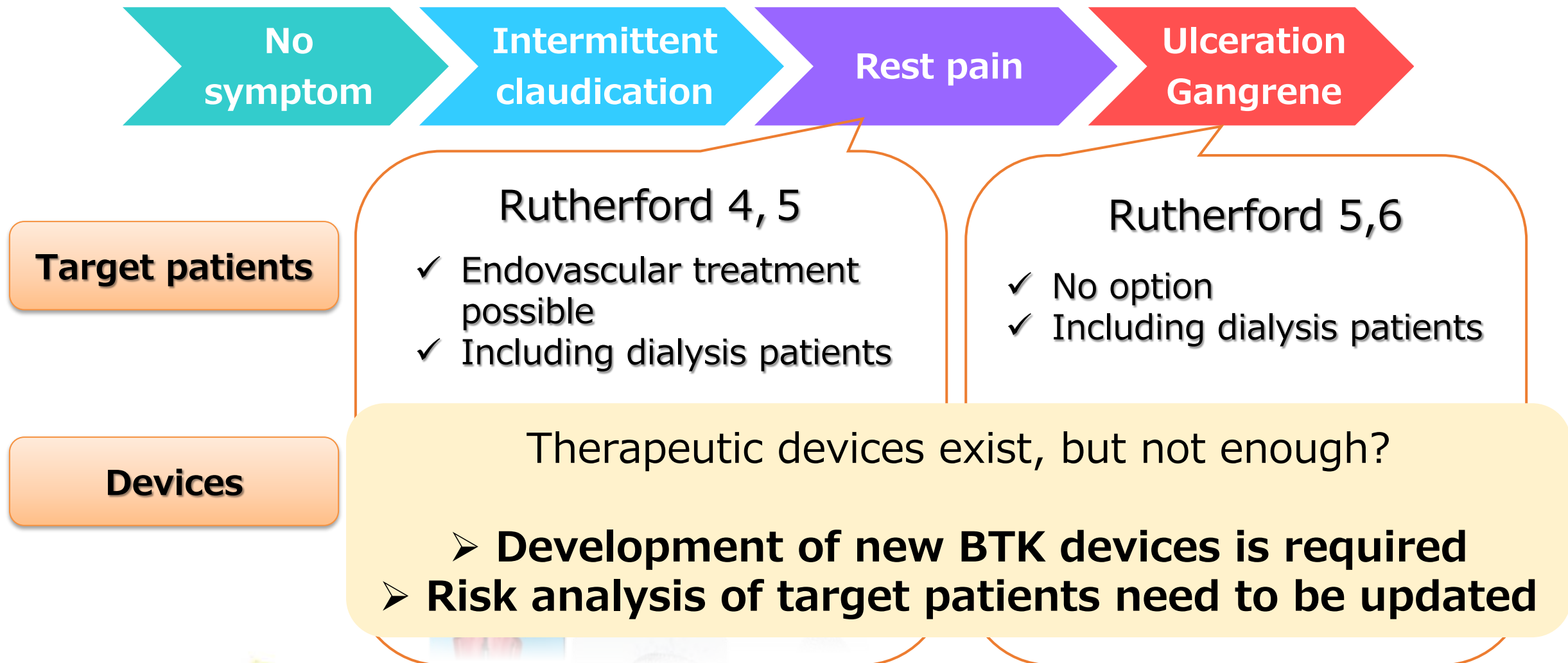
- A basic framework of global clinical trials for CLTI devices considering differences in patient characteristics and medical environments between the countries.

* 1 : PFSB/ELD/OMDE No.1 of 2013, dated May 29, 2013

* 2 : H. Yokoi et al., Circ J. 2018 Aug 24;82(9):2233-2239



Target patients and devices for CLTI treatment devices



The basic concept of review of BTK devices

Treatment purpose : Improve clinical outcome by increasing blood flow in lower limbs



Endpoints : Device performance and therapeutic success

1. Maintenance of vessel patency
2. Improvement of clinical symptoms
 - Pain relief, QOL
 - Wound healing
3. Avoidance of limb amputation



Comprehensive evaluation is important.

Discussion Points

To discuss more appropriate strategies to consider both characteristics of individual devices and factors that influence clinical outcomes

Patient selection

- Specification of target patients for those devices can show their efficacy
- Definition of lesions that can assess device performance
- Difference from the patients in real-world

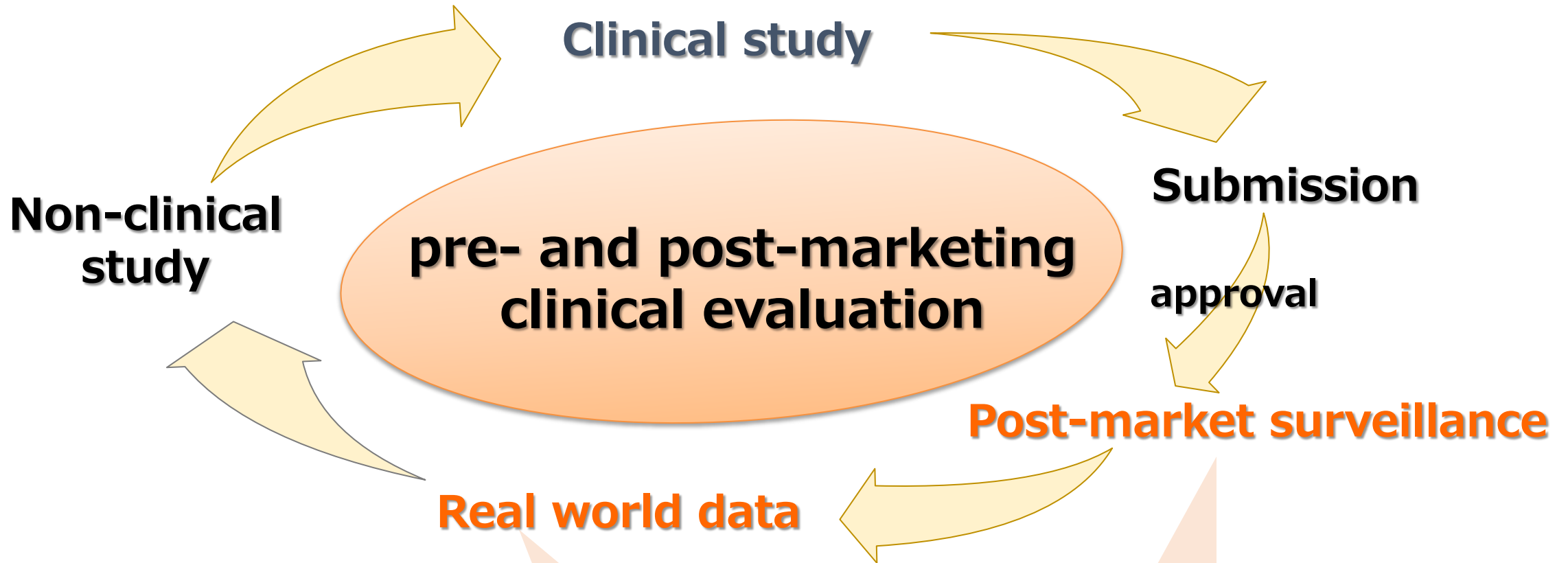
Endpoint

- Standardizing clinical success of EVT for CLTI patients
- Gap between vascular patency and wound healing
- Clinically-significant duration of patency or wound healing

Evaluation method

- Standardizing vascular patency and foot perfusion assessment
- Objective assessment of pain relief and wound healing
- Unification of index procedures and wound treatment

Utilization of post-market data



- Confirmation of long-term data
- Efficacy and safety evaluation for more various patients
- Consideration of appropriate patient selection strategies
- Review of guidelines for proper use etc...

To promote the development of innovative devices

Reconsideration of the evaluation strategy promote the development of new CLTI devices based on the current status and challenges of development and the characteristics of new devices.

➡ It is important that industry, academia and regulators continue discussions to find the direction for development and the appropriate evaluation strategy.

Let's work together to provide patients and medical professionals with faster access to safer and more effective devices!

Industry

ALL JAPAN!

Academia

Regulatory