

LLIN Durability

PQT-VC Perspective

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WHO Prequalification – Vector Control

RBM Vector Control Working Group LLIN Workstream

Prequalification Approach

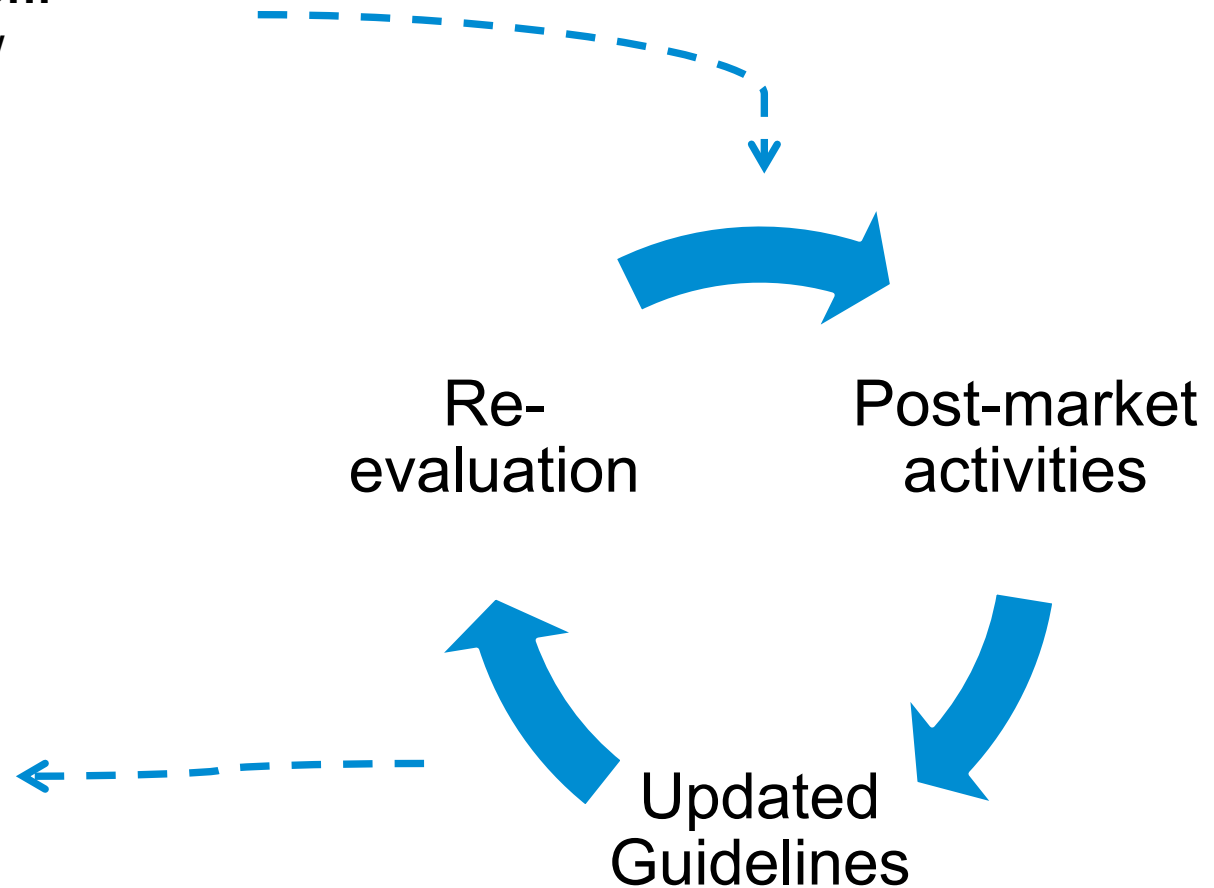
Oversight of the product through out its lifecycle

- Prequalification before access
 - review of data / information
 - input to labelling
 - decision document
 - prequalification listing
- Post market activities after prequalification
 - Inspection(s)
 - change submissions
 - complaints
 - **Surveillance and Monitoring**

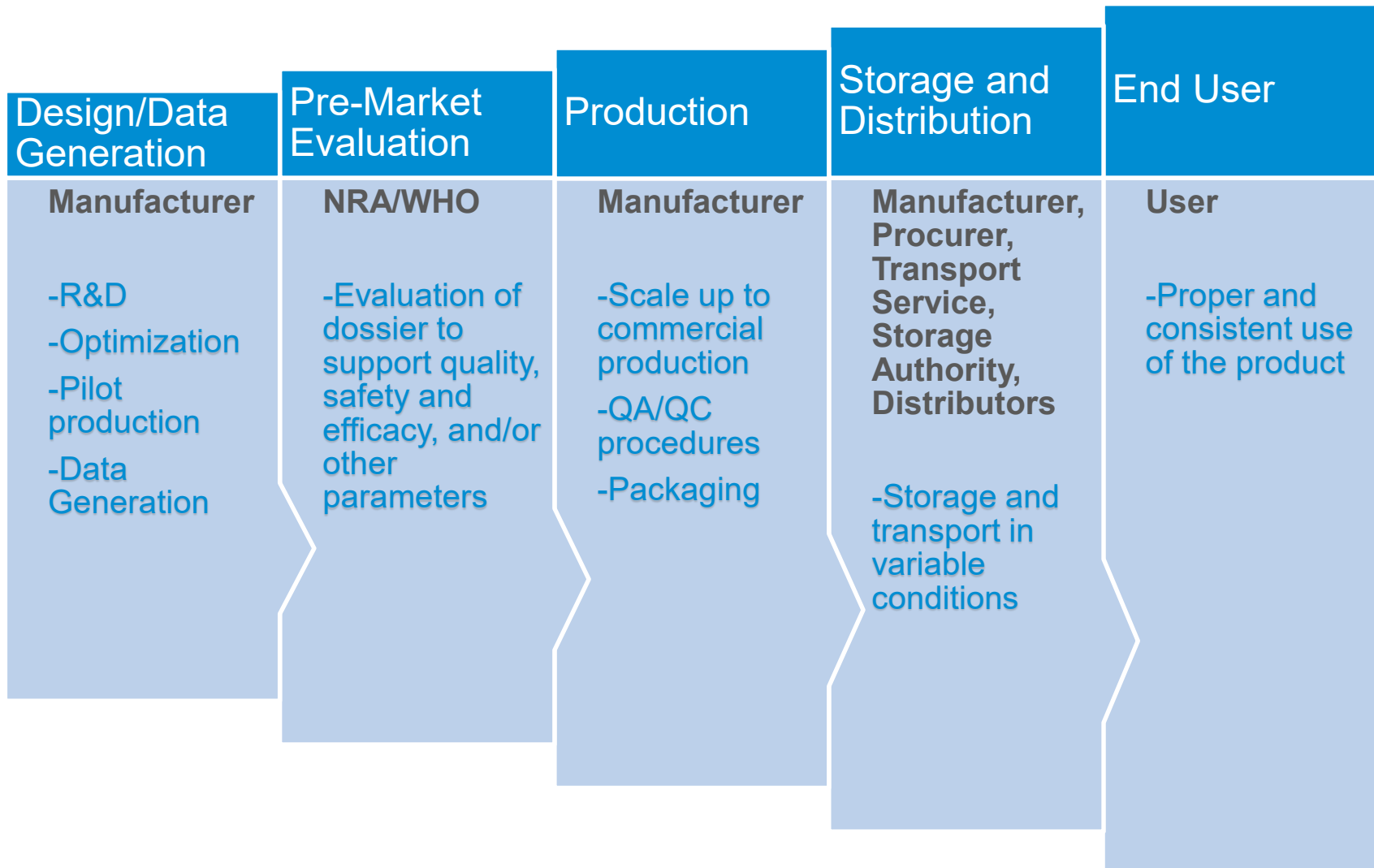
Regulatory Lifecycle

Pre-market evaluation:
Conversions and New applications

End of Product Life-cycle:
Withdrawal or Delisting



Critical Stages which may impact ITN Durability



Partnerships in Managing Durability

- Manufacturers
- National Regulatory Authorities
- WHO
- Procurers
- Transport Services
- Storage Authorities
- National Control Programs
- Researchers



PQ Perspective - Definitions

- **Insecticide treated net (ITN)**
 - ITNs are bednets which contain an insecticide, either coated onto the fibres or incorporated into the fibres, which are meant to repel, kill, or mitigate the target vector so as to enhance the personal protection from the bednet, including in the case of damage to the net in the form of holes, as well as impart community protection through the impact on mosquito population, biting rates, and sporozoite infection rates.
- **Long Lasting Insecticidal Nets (LLINs)**
 - **LLINs** are those ITNs which have been shown to meet the WHO standards for retained active ingredient content and bioefficacy over 20 washes (to correlate with a 3 year useful life). Manufacturers are expected to provide chemical and bioefficacy data to support the claim of Long Lasting/LLIN.

PQ Perspective - Components of Durability

Chemical Durability

- informed by the nominal concentration of the active/synergist substance(s) at the time of manufacturer which establishes the total “reservoir” of AI(s).

Residual Bioavailability

- is an extension of the chemical durability, specifically focused on the surface concentration of the AI(s) on the fibre.

Physical Durability

- is a function of the production (design, materials, treatment, knitting, and sewing) and the use of the product. ITNs are intended to maintain their physical integrity for 3 years to coincide with the designed chemical durability and targeted residual bioavailability.

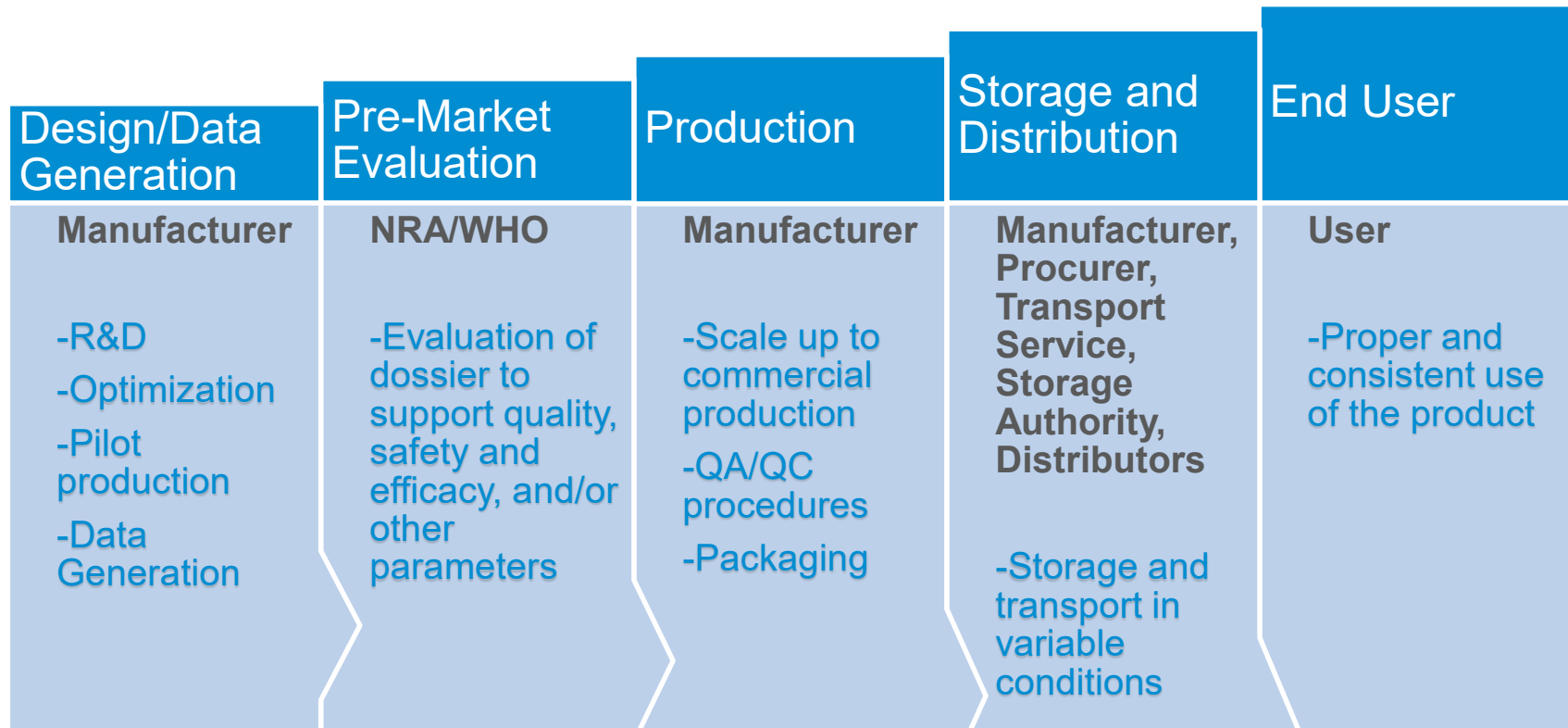
PQ Perspective - LLIN Durability

- Durability of insecticide treated nets deployed and used in the field is a critical component to ensuring access to an effective product
- Pre-market data provides information / data but this is generated under controlled conditions.
- The product is prequalified with the understanding (and supported by data) that it will be effective for the expected lifecycle under normal use conditions
- Post market monitoring and surveillance provides information about the real world use of the product that can be used to confirm the premarket findings and inform on aspects associated with the product lifecycle, eg., what conditions impact durability.

Other factors which inform the PQ Perspective

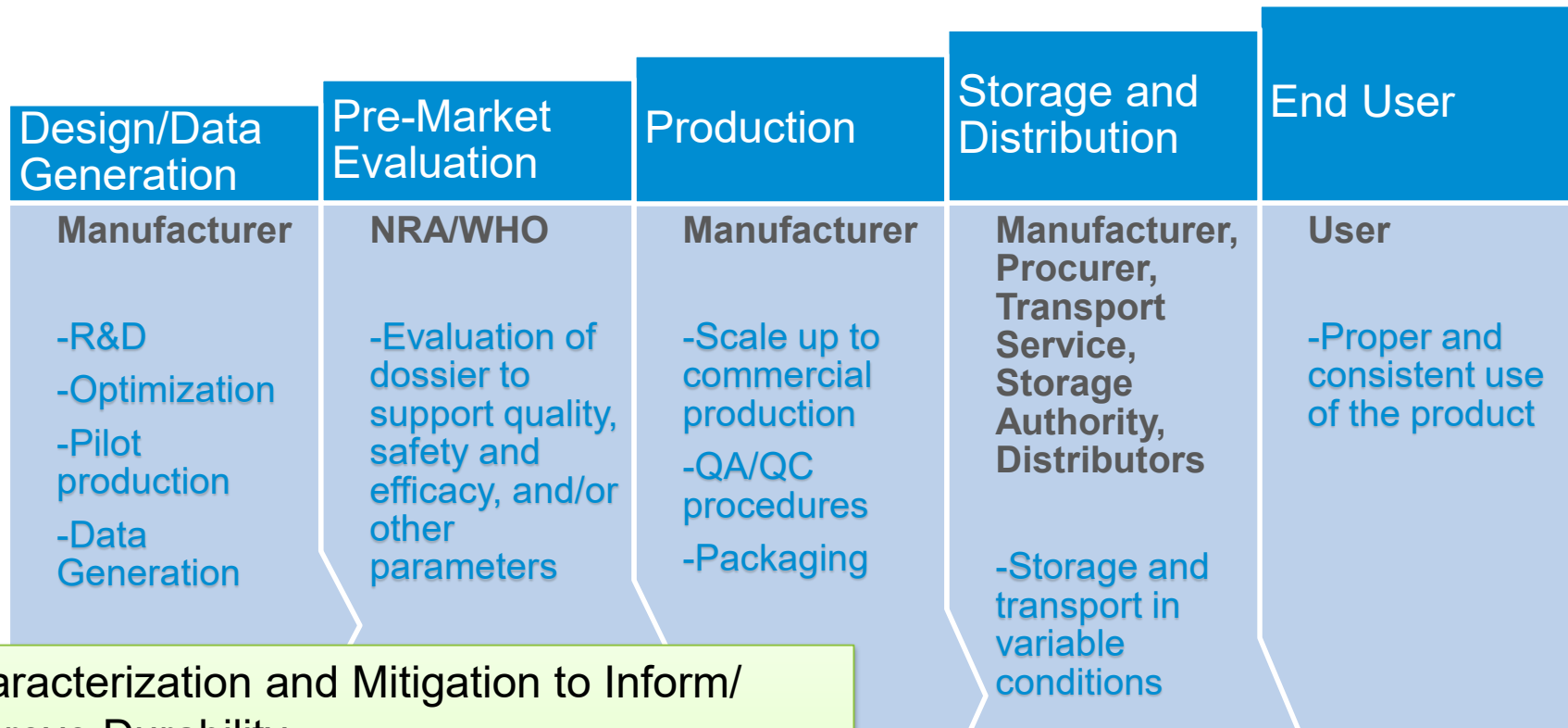
- Current Policies
 - 20 washes
 - 3 years
- Current data requirements for prequalification (questions)
 - Are these useful in informing durability
 - Do we need different and/or additional data /information
 - Current policies
 - Should the process of prequalification include post market commitments
- Product complaints
 - AI content
 - Storage and Stability
 - Storage conditions

Managing Durability



DURABILITY STRESSORS ->
 packaging + pressing + heat + water + light + washing + fire + animals + standard use + misuse + ...

Managing Durability



Characterization and Mitigation to Inform/Improve Durability:

- Additional Data Requirements
- Consistent/value added specifications
- Label Language/Storage conditions
- Post market activities
- Feedback from partners – Generic
- Feedback from partners – Product specific
- Supporting Information/Education Campaigns

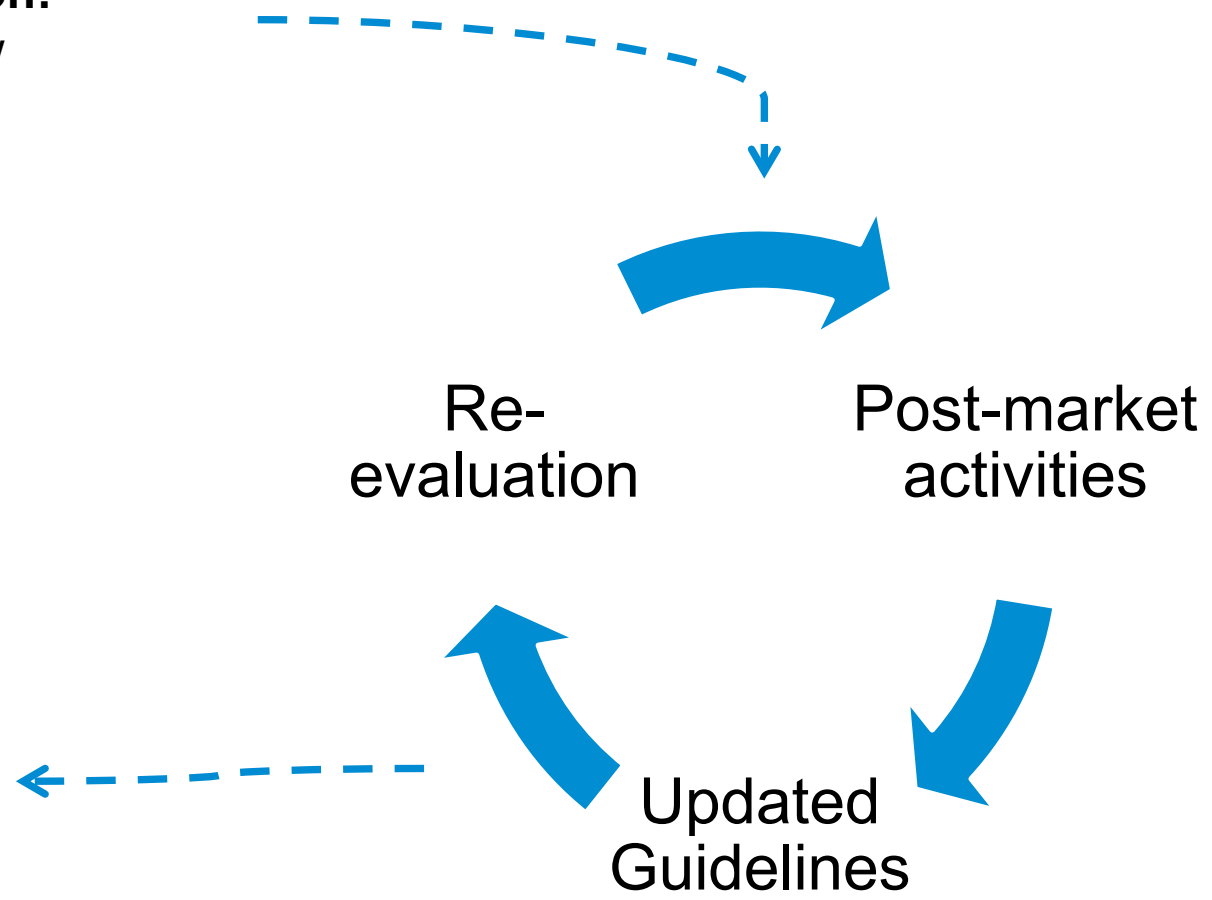
MANAGE →

DURABILITY STRESSORS -> packaging + pressing + heat + water + light + washing + fire + animals + standard use + misuse + ...

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Thank you