

RTI HEALTH SOLUTIONS®

NICE STA Process

Industry / Submission perspective

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LEADING RESEARCH...
MEASURES THAT COUNT

STA Process

- Announced by NICE in November 2005
- Finalised in May 2006 following consultation process & experience from first submissions
- RTI-HS experience
 - Interim process – Taxotere for early breast cancer (successful)
 - Final process – 2 submissions (ongoing)
 - Model development & submission dossiers

STA Process

- Opportunities
- Process
 - Submission of Evidence
 - Consultation process
- Challenges & Unknowns
- Recommendations

Opportunities

- More rapid guidance
- Focus on single intervention vs standard care
- Opportunity for greater clarity in decision problem

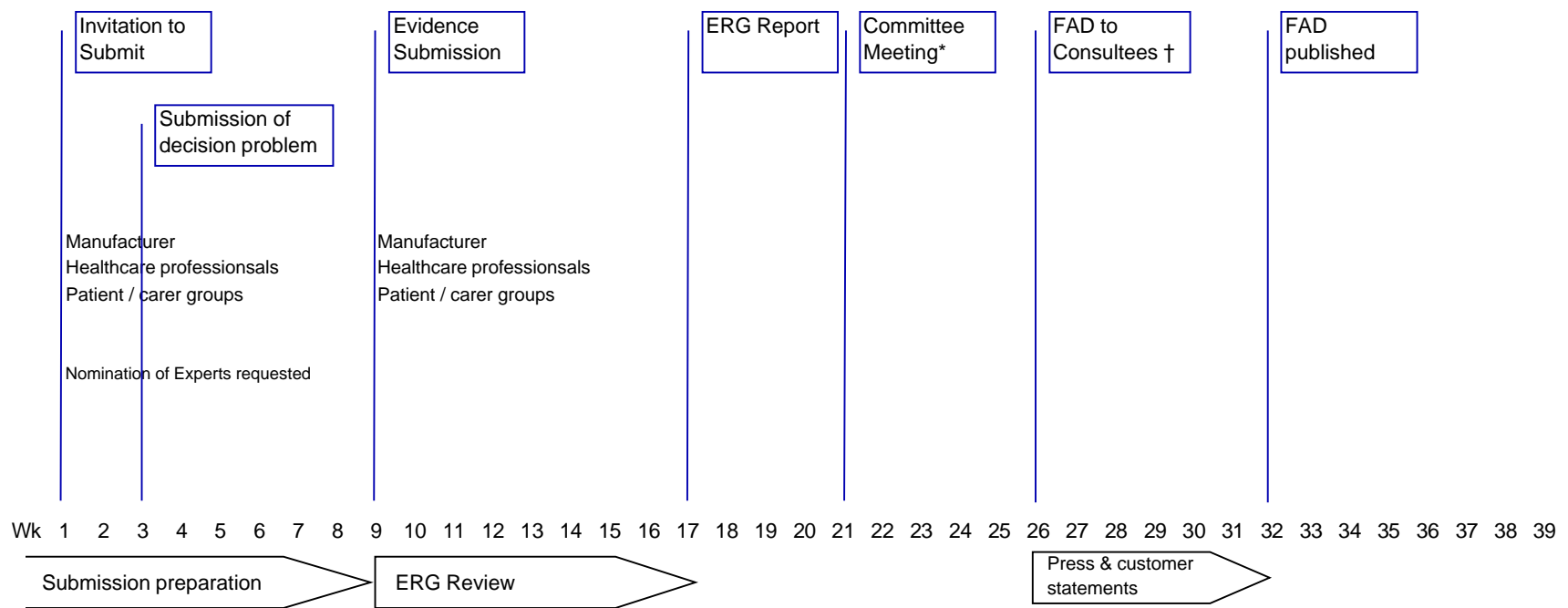
Opportunities

- More rapid guidance
- Focus on single intervention vs standard care
- Opportunity for greater clarity in decision problem
 - Scope developed by NICE in consultation with consultees and commentators
 - Manufacturer required to submit a summary of the decision problem
 - 2 weeks from formal invitation
 - Includes population, intervention, comparators, outcomes
 - NICE will provide assistance in specifying the decision problem (on request)

Process

- Evidence Submission
 - Greater degree of specification of submitted evidence
 - Q & A format
 - Word count restrictions
 - Mandatory submission of Model
 - Requirement for budget impact analysis?

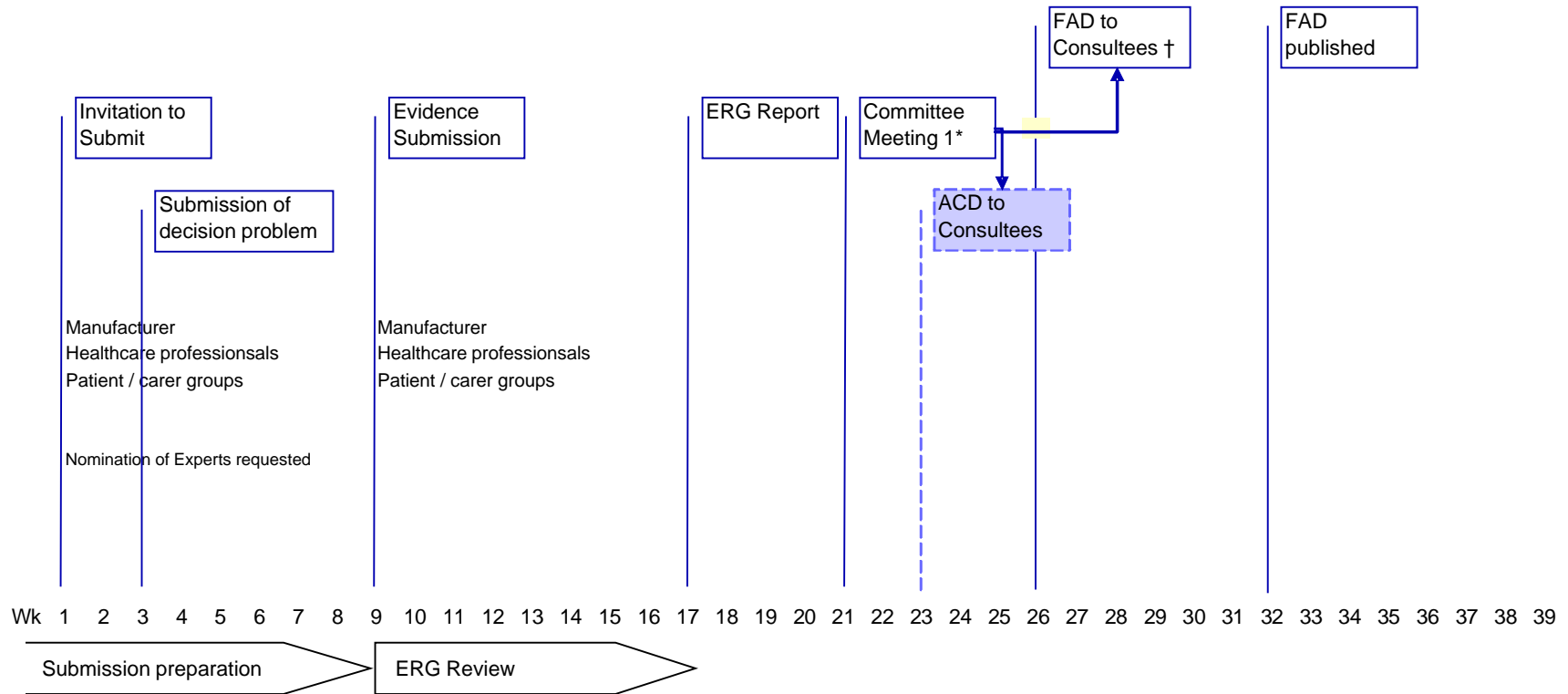
Process



* Positive CHMP Opinion Required to Proceed

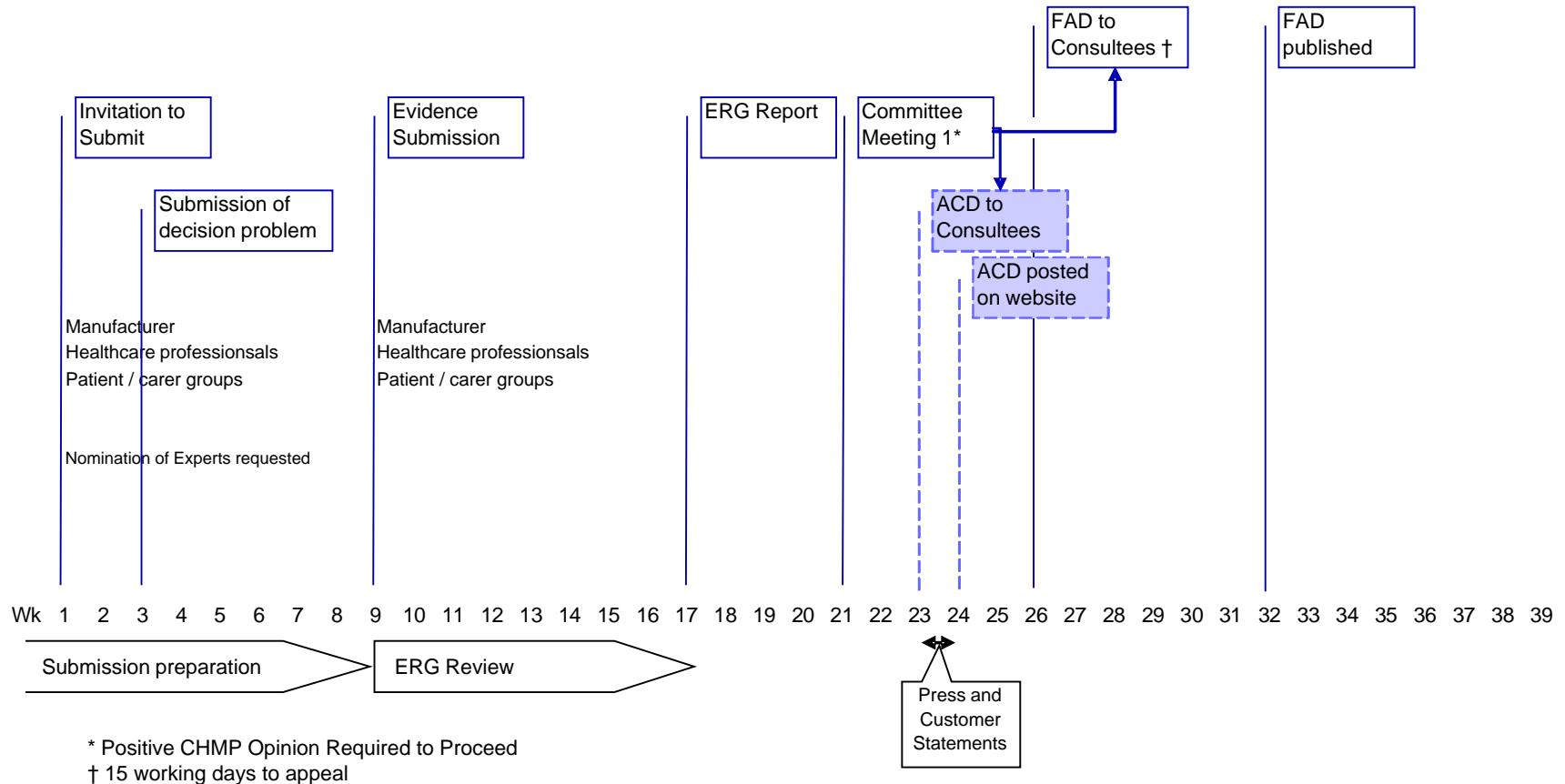
† 15 working days to appeal

Process

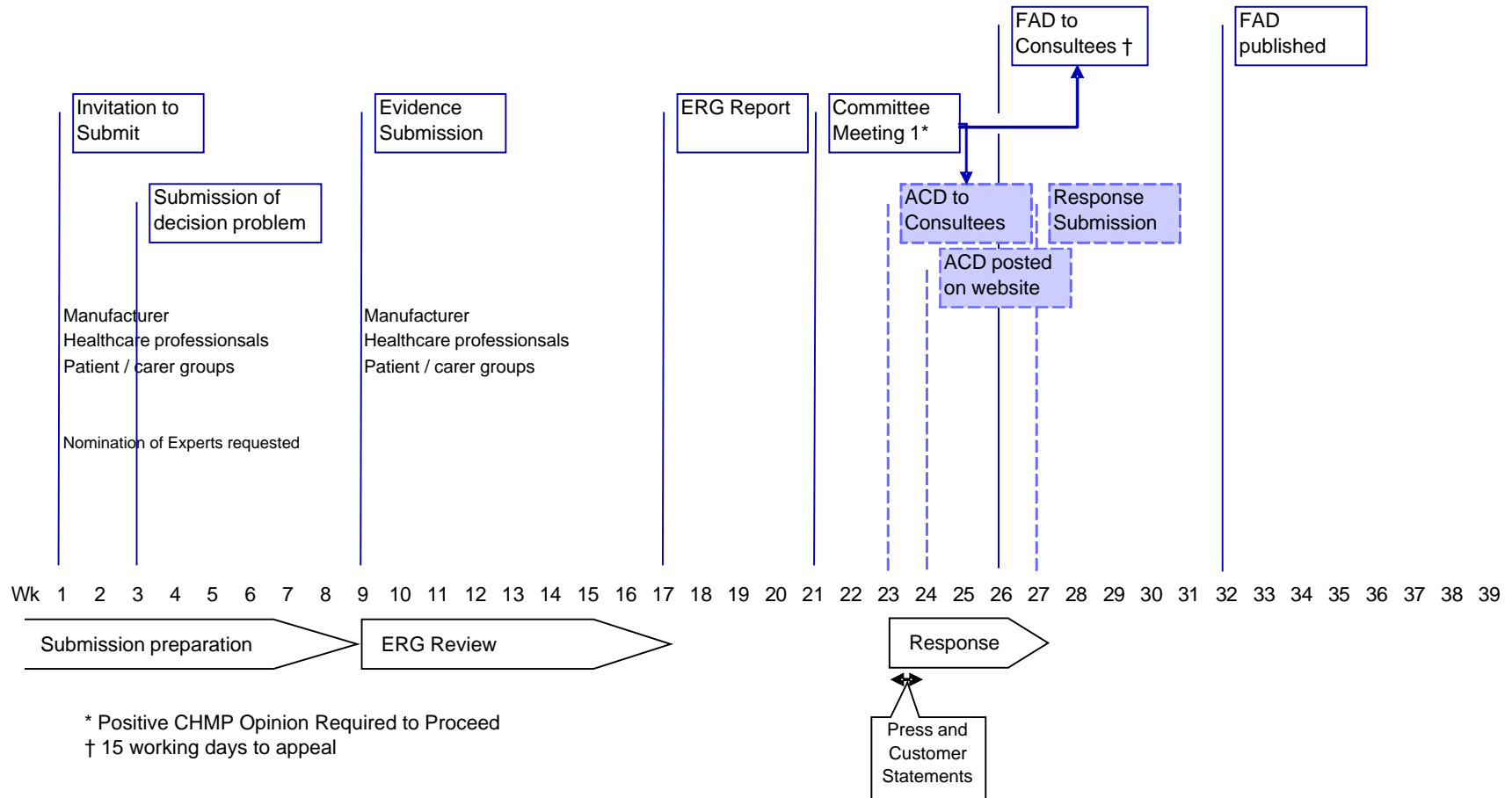


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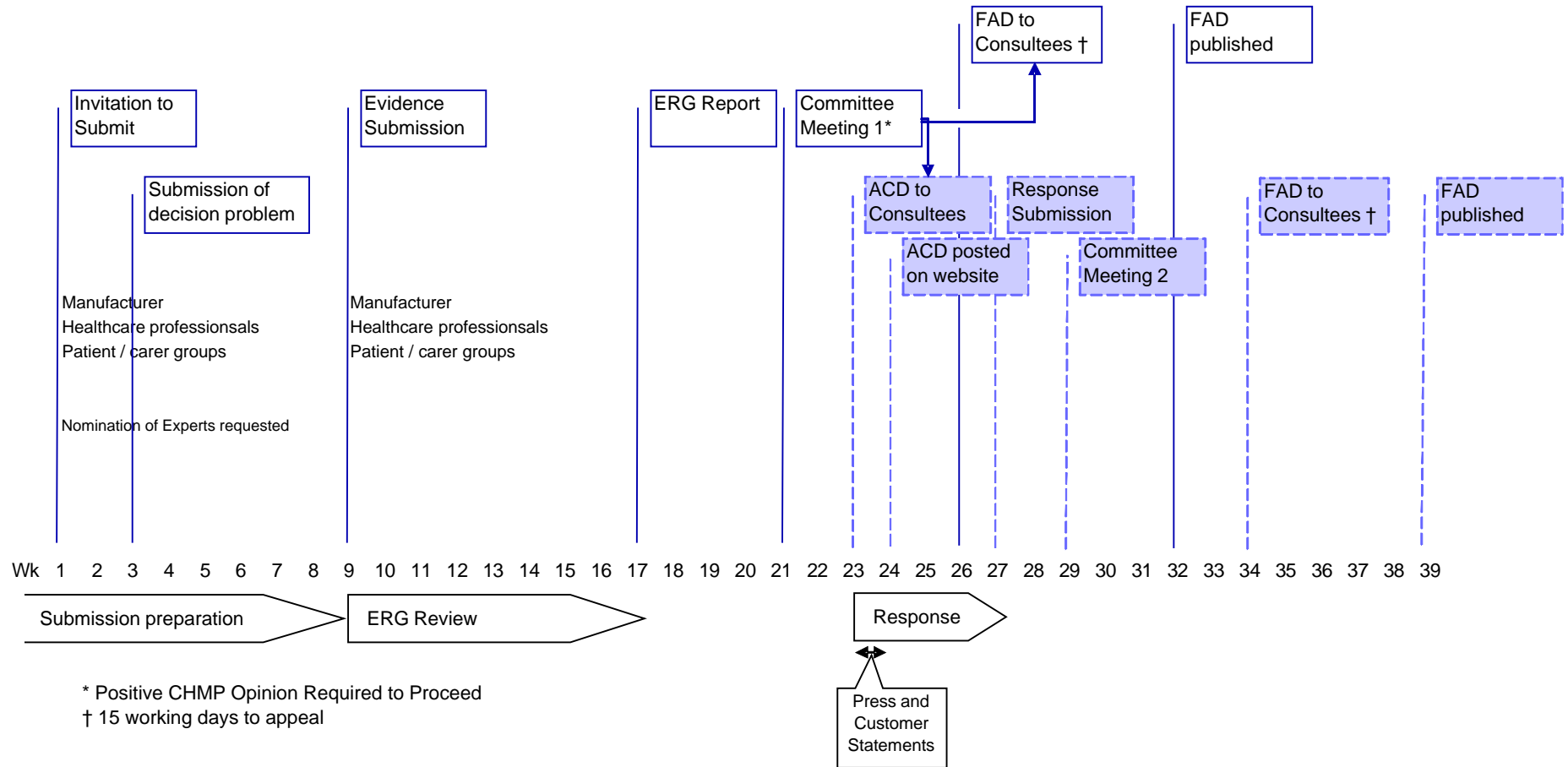
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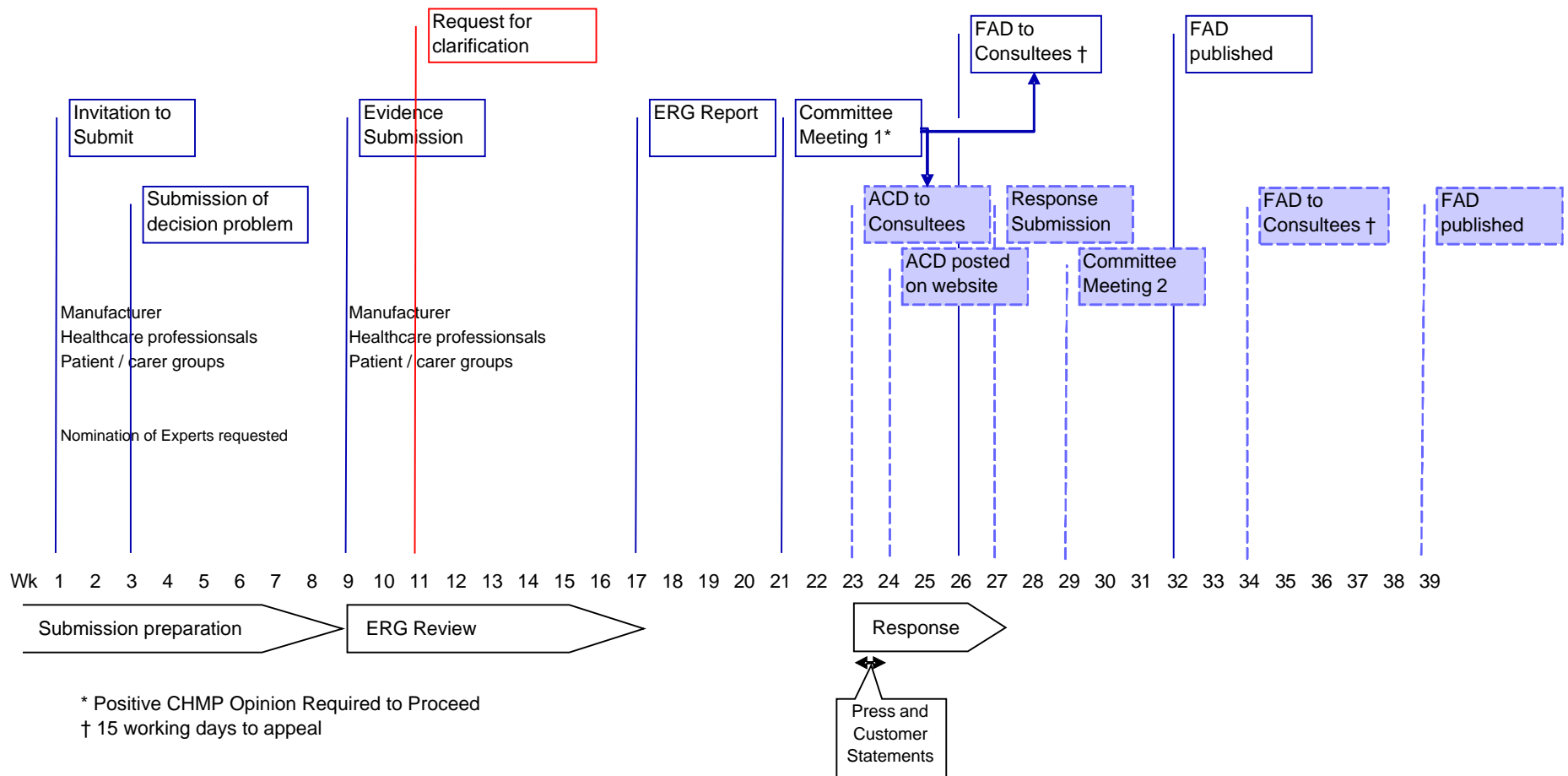
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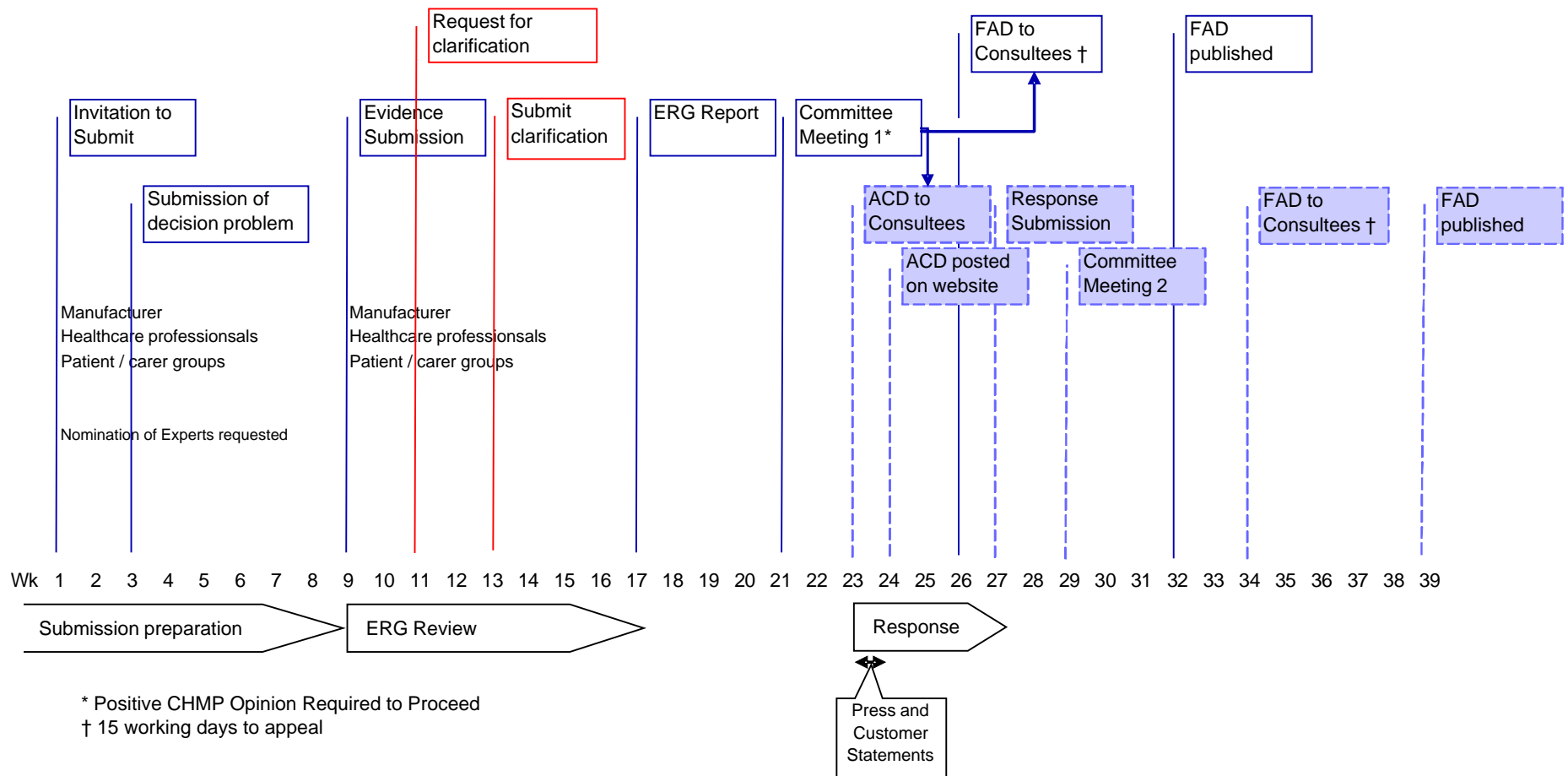
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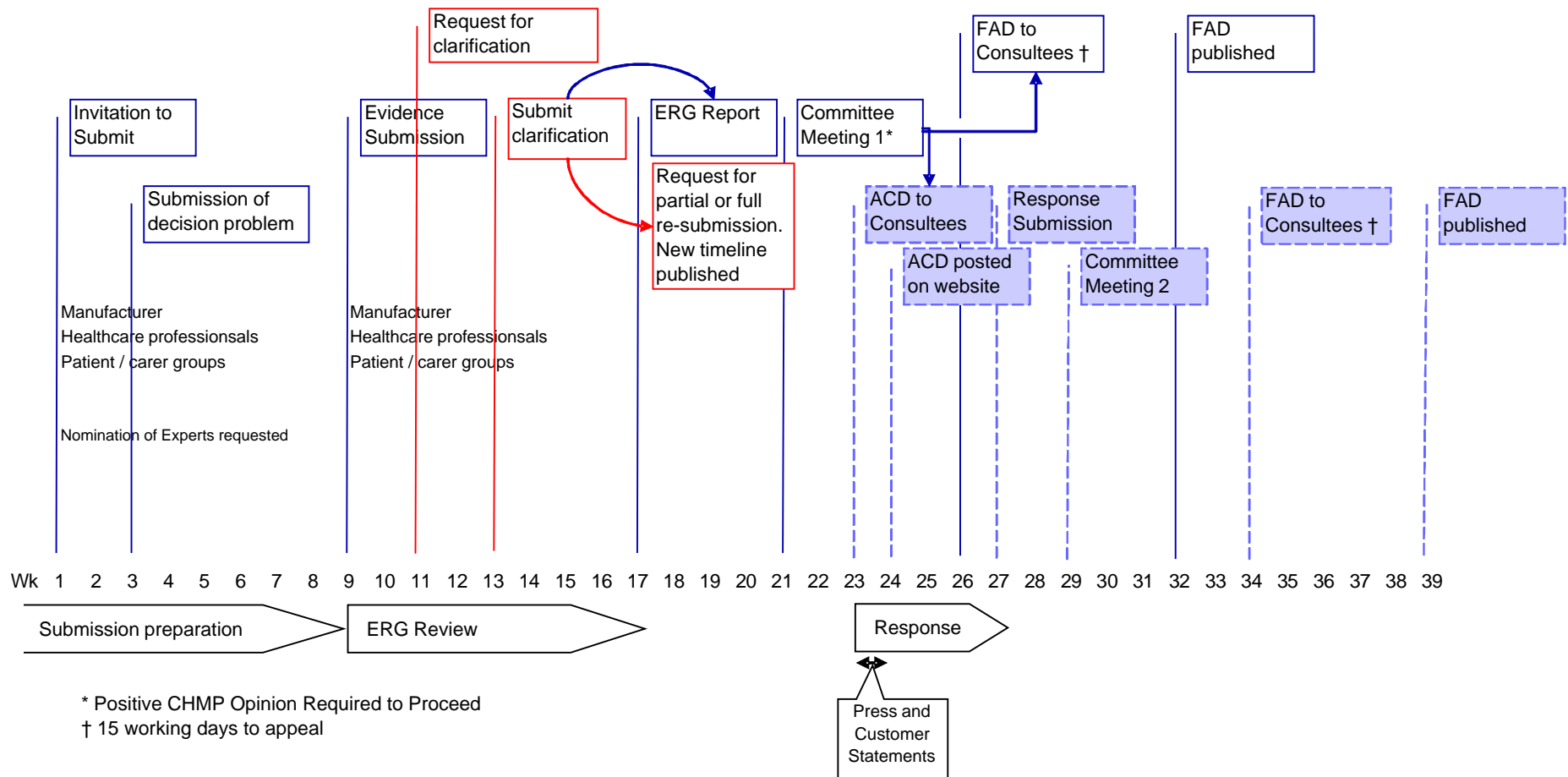
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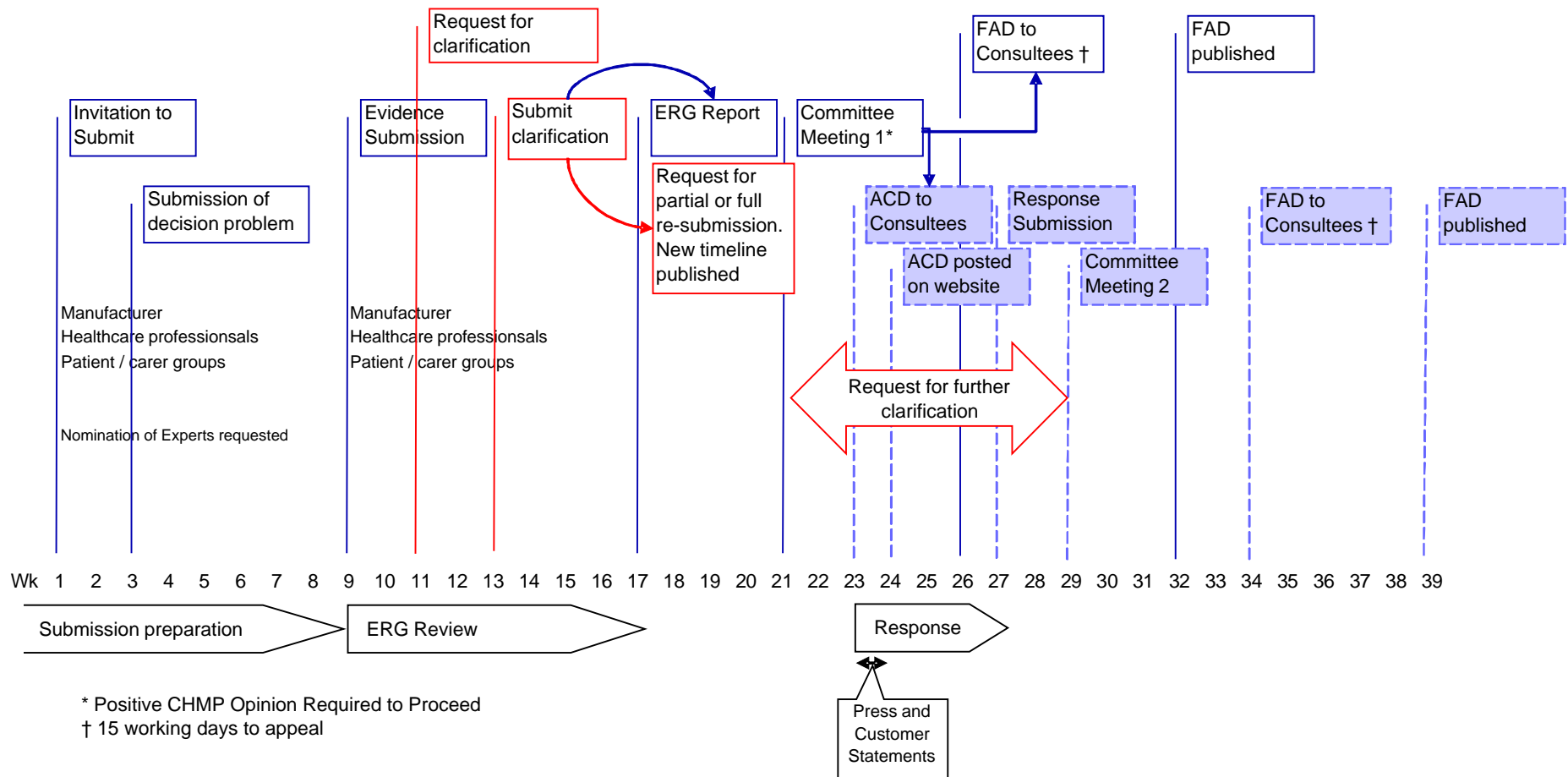
Process



Process



Process



Challenges

- Burden of evidence generation on sponsor
- Timescales for responses

Unknowns

- Will appraisal be by STA or MTA
- Will ERG model be commissioned
- Will MTA be performed at a later date

Recommendations for Manufacturers

- Engage with NICE to define the decision problem
- Schedule resource for
 - Requests for clarification
 - 2 weeks after submission (2 wks for response)
 - After 1st committee meeting (~3 wks for response)
 - Response to ACD
 - Appeal
- Perform scenario analysis prior to scheduled receipt of ACD for
 - Preparation for response
 - Preparation of communications (internal, stakeholders, press)