EMA-HTA Parallel Scientific Advice

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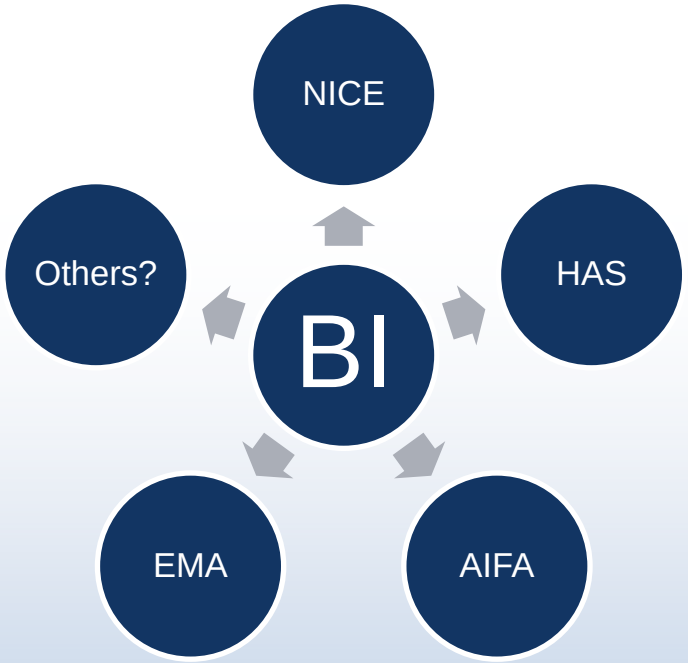
Background

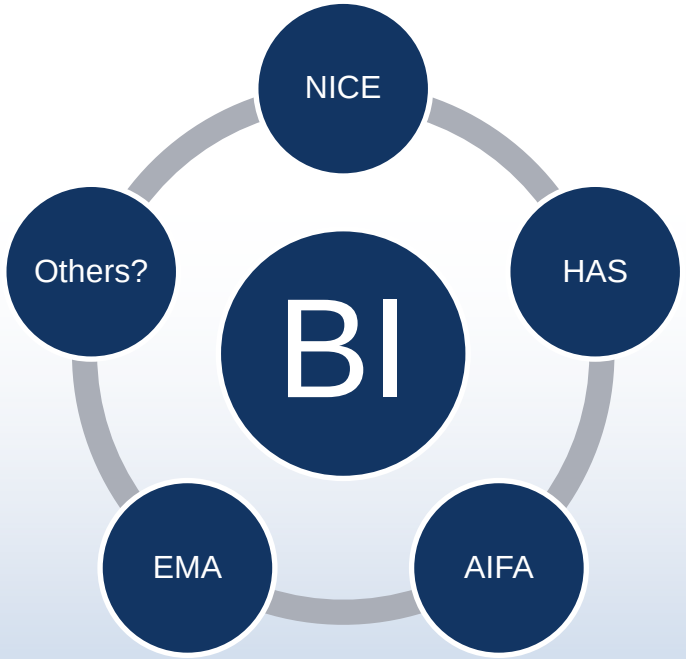
- BI went through parallel scientific advice in 2017 for BI1467335 in NASH
- Many learnings from the process
- Aim of this presentation is to provide an industry perspective on the value of the process
- A few caveats:
  - Process has changed since last year
  - Presenter not involved through full process

The process – an industry perspective

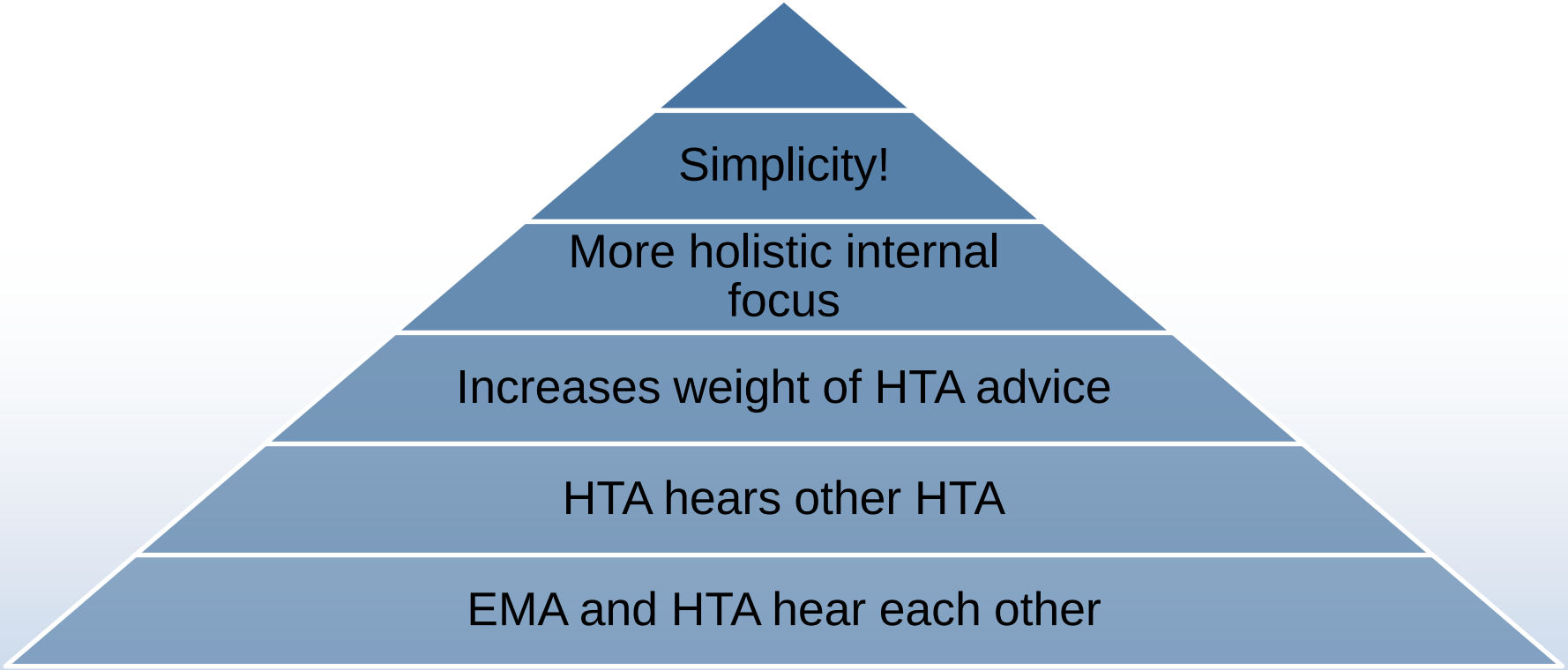
Without PSA



With PSA



Why PSA – an industry perspective



What did BI get out of the process?

- Actionable advice
  – E.g. including a small number of F1 patients in Phase 3 trial
- Opportunity to engage in detail with payers
- Opportunity to inform HTA bodies on your specific disease area and therapy
- Understanding of different perspectives of HTA bodies and EMA
- Better internal understanding of PSA process
- Better chance of designing a trial that meets both EMA and HTA requirements

Limitations

- Does not include the US
  - EMA-FDA PSA possible
  - EMA-HTA PSA possible
  - EMA-FDA-HTA PSA not possible understandable; but means EMA-HTA PSA is not always the right decision
- Limited country representation of HTA (not all participate in every process, but probably enough to get a good picture)
- Output of advice varies by HTA agency
- Long process – some advice takes a long time
- Circumstances change – what was true last year may not be true in X years time (this is common for any advice meeting)

Conclusion

- Output and learning through process very valuable
- Not always the right process to choose (sometimes EMA-FDA, sometimes not needed if already have good knowledge of an area)
- From an ‘industry as a whole’ perspective, the more we align with regulatory **and** payer needs, the better chance we have of designing trials that can achieve both an indication **and** reimbursement