

Evidence Requirement for IVDs

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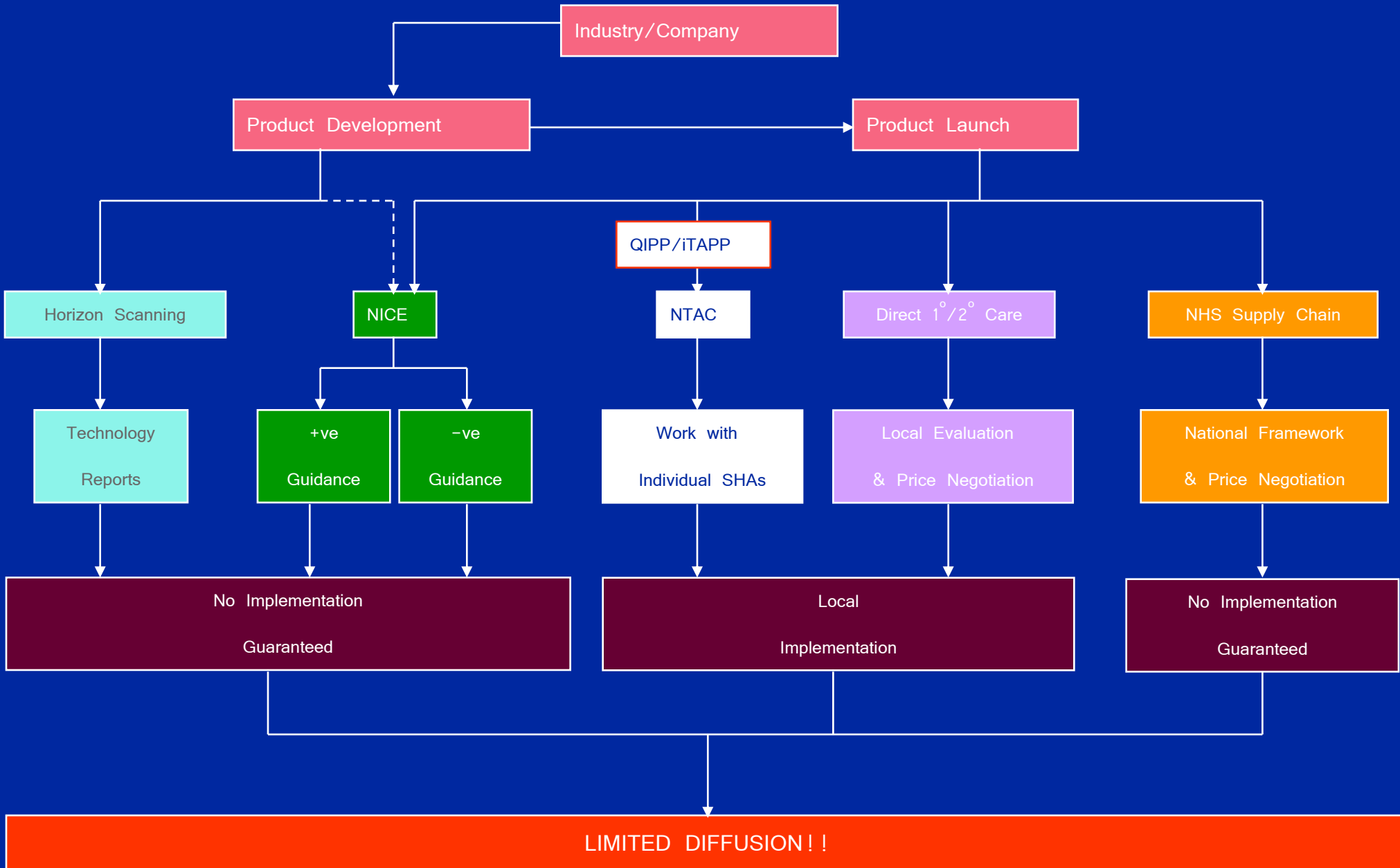
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SETTING THE SCENE - Diagnostic Overview



Evidence Requirements

Horizon Scanning / NICE

- Company technical reports
 - CE / CE IVD
 - Minimum level to market product
- RCTs
 - Market Potential vs. cost of RCTs
 - Market size determines the resource put towards clinical evidence
- Cost-effectiveness
 - Evidence required to show cost-effectiveness relies on clinical utility and outcome evidence (QALYs)
 - Providing outcome data is challenging for Dx
 - Health economic modelling is an alternative
 - Limited evidence requires assumptions
 - Validity often challenged
 - Limited or no adoption

Evidence Requirements

QIPP / iTAPP / 1° / 2° Care

- Clinical value
 - Clinical evidence
 - Benefit to the patient
 - Benefit to the healthcare professional
 - For the UK
- Financial / cost savings
 - Benefit to healthcare system
 - Cash savings for FTs/NHSTs/PCTs/CCGs
- Management / roll out
 - Service improvement / service re-design / decommissioning
 - Local 'real-life' examples
 - Help to evidence all of the above

Evidence Requirements

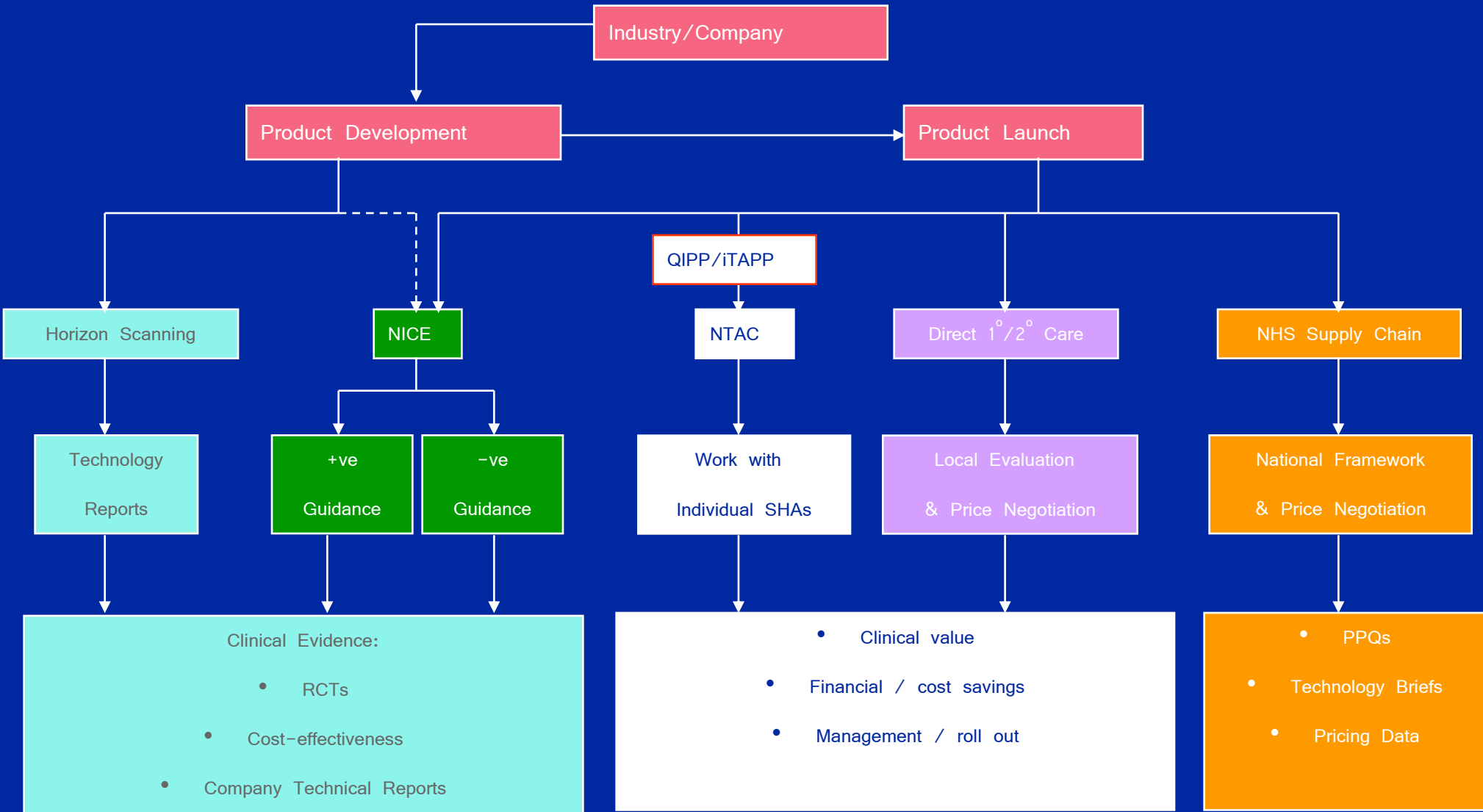
NHS Supply Chain

- Pre-Purchase Questionnaires
 - Intended use
 - CE Mark
 - Safety / Quality Standards

- Technology Briefs
 - Supplier details
 - Testing need, setting, clinical area,
 - Patient benefits, cost benefit (summaries)

- Pricing Data
 - List price
 - Discount structures / dependencies

EVIDENCE REQUIREMENTS – Diagnostic Overview



Evidence Requirements

Barriers to Technology Uptake

- Wide and varied profiles of Evidence requested
 - Could the profile of evidence be simplified ?
- QALY's
 - Recognition & acceptance of alternative appropriate methods to evaluate diagnostics
- Time taken / Cost of generating Evidence supporting diagnostic technologies
 - Companies working to shorter timescales to develop and launch products
 - Large multi-centre studies / RCTs increase time to market and cost of technology
- Relevance of Evidence to local healthcare environment
 - Generation of Evidence in UK
 - No formal structures or systems for generating Evidence in UK

Points to Consider

- Development of diagnostics different to pharmaceuticals;
 - Shorter development timelines
 - Lower levels of evidence required to place on market;
- Diagnostics technologies usually gain clinical utility data post launch
 - Process can be accelerated if NHS readily accepts novel technologies & works with companies to acquire data
- QALYs can be used for evaluation of appropriate forms of diagnostics
 - E.g. companion diagnostics
- For more conventional diagnostics, evaluate in the context of the benefit it will bring to the relevant part of the overall care pathway
 - E.g. serum biomarkers for heart failure reducing echocardiogram referrals (rule-out); increasing the number of correct referrals
- Studies looking at time to diagnosis, ease of use, resource use (reduced referrals), etc... are more likely to reflect value of diagnostic technologies

Observations / Needs

- Clear and simplified profile of Evidence that effectively supports commissioning processes and decisions
- Sufficiently funded collaborative initiatives involving the NHS, R & D centres and industry
 - NHS more readily exploring use of novel technologies & working with companies to acquire Evidence – Can this be formalised in some way ?
 - NICE acting as facilitator for any technologies requiring further research (this initiative is welcome !)
 - R & D infrastructure (eg. NIHR / NOCRI) enabling ‘low cost’ research models to generate evidence necessary to support uptake of diagnostics ?? (this initiative would also be welcome !!)



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