## Development Stages (Therapeutics, Vaccines and Devices)

### Level S1. Target identification
- Therapeutic target identified

### Level S2. Target validation
- Therapeutic target undergoes validation in appropriate models

### Level S3. Therapeutic identification
- Drug/biologic: Small molecule or biologic with potential for therapeutic effect is identified
- Device: Concept for new device is identified

### Level S4. Therapeutic design
- **Drug**: Lead molecule is identified
- **Biologic**: Mechanism of action studies are performed
- **Vaccine**: Antigen is identified
- **Device**: Initial device design is established

### Level S5. Therapeutic optimization
- **Drug**: Lead compound is optimized
- **Biologic**: Product is generated
- **Vaccine**: Vaccine candidate is produced
- **Device**: Device design is optimized
- Clinical development plan is prepared

### Level S6. Preclinical I
- Pharmacologic/animal model studies demonstrating proof-of-principle are performed

### Level S7. Preclinical II
- Dose-finding/characterization studies are performed

### Level S8. Preclinical III
- **Drug**: Toxicology/safety studies are completed
- **Biologic/vaccine**: Scale-up manufacturing finalized

### Level S9. Clinical Phase I
- Drug/biologic/vaccine: Human testing on a small-scale basis

### Level S10. Clinical Phase II
- Drug/biologic/vaccine: Controlled clinical testing has been conducted in a relatively small number of patients
- **Device**: Scale-up and manufacturing

### Level S11. Clinical Phase III
- Drug/biologic/vaccine: Clinical testing in large patient populations
- **Device**: Marketing, sales and distribution

### Level S12. Patient use
- Drug/biologic/vaccine: Clinical trials completed and technology approved and available for use – post-marketing surveillance (if required) ongoing
- **Device**: Post-marketing surveillance ongoing
## Development Stages (Biomarkers)

<table>
<thead>
<tr>
<th>Level SB1. Discovery</th>
<th>Definition of differential expression of specific biomarkers (diseased versus control)</th>
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</thead>
<tbody>
<tr>
<td>Level SB2. Qualification</td>
<td>Confirmation of candidate biomarkers using alternative test methods</td>
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<tr>
<td>Level SB3. Verification</td>
<td>Extension of analysis to greater number (e.g. 100s) of patient samples incorporating a broader range of cases and controls; Affirmation of biomarker candidate sensitivity and specificity</td>
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<tr>
<td><strong>Level SB4. Assay Optimization</strong></td>
<td>Development of the assay in a clinically relevant format</td>
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<tr>
<td><strong>Level SB5. Validation</strong></td>
<td>Finalized assay format is tested against large number (e.g. 1000s) of human patient samples that reflect the full variation of the targeted population</td>
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<tr>
<td><strong>Level SB6. Patient use</strong></td>
<td>Clinical trials completed and technology approved and available for use – additional studies may be ongoing to evaluate whether the test influences positively the ultimate health outcome of tested patients</td>
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</table>

- **Identification**
- **POC**
- **Regulatory**
- **Clinical**

**POC**

**Lower Priority**

**Higher Priority**
Development Stages (Software)

**Level SS1. Discovery**
- Concept for new software is identified

**Level SS2. Pre-alpha - Development**
- Requirements analysis, software design, software development

**Level SS3. Pre-alpha - Optimization**
- Software debugging

**Level SS4. Pre-alpha – Initial testing**
- Initial testing within the development team

**Level SS5. Alpha - Testing**
- Initial testing with users outside the development team

**Level SS6. Beta – Testing**
- Software is feature complete. Focus of beta testing is reducing impacts to users. Usability testing

**Level SS7. Release Candidate**
- Beta version with potential to be final product. Software ready to be delivered or provided to customer