Assessment Framework In Israel
WCBP January 2018, Dr. Vered Ben Naim

Applications

“Regular” pathway
Accelerated pathway

Regulation
Pharmacist’ Directive & Regulations
IMOH guidelines
ICH & EMA guidelines adoption
FDA & WHO guidelines
EP/ USP/ JP

Requirements
Full Dossier
CPP
FDA/EMA assessment reports
Questions & Answers

Making a Decision
Full Assessment
Advisory Committee
Risk-Balance approach
Current Regulation Framework - Advance Therapies

**Legislation**
- Definition of a Medicinal Product
- Cell and Tissues supervision and enforcement

**Hospital Exemption - EU model**
- In hospitals
- Under physician’s responsibility
- Justification for CL exclusion
- Under GMP, Unique Quality standards
- Tractability

**GMP**
- EC Directives & guideline
- Flexibility
- Risk-based approach
- Case by case

**Clinical trials & Licensing**
- IMOH guidelines
- Classification
- EMA guidelines
- Ad-hoc advisory committee