Re-Designation and Transitional Period Impact on Manufacturers

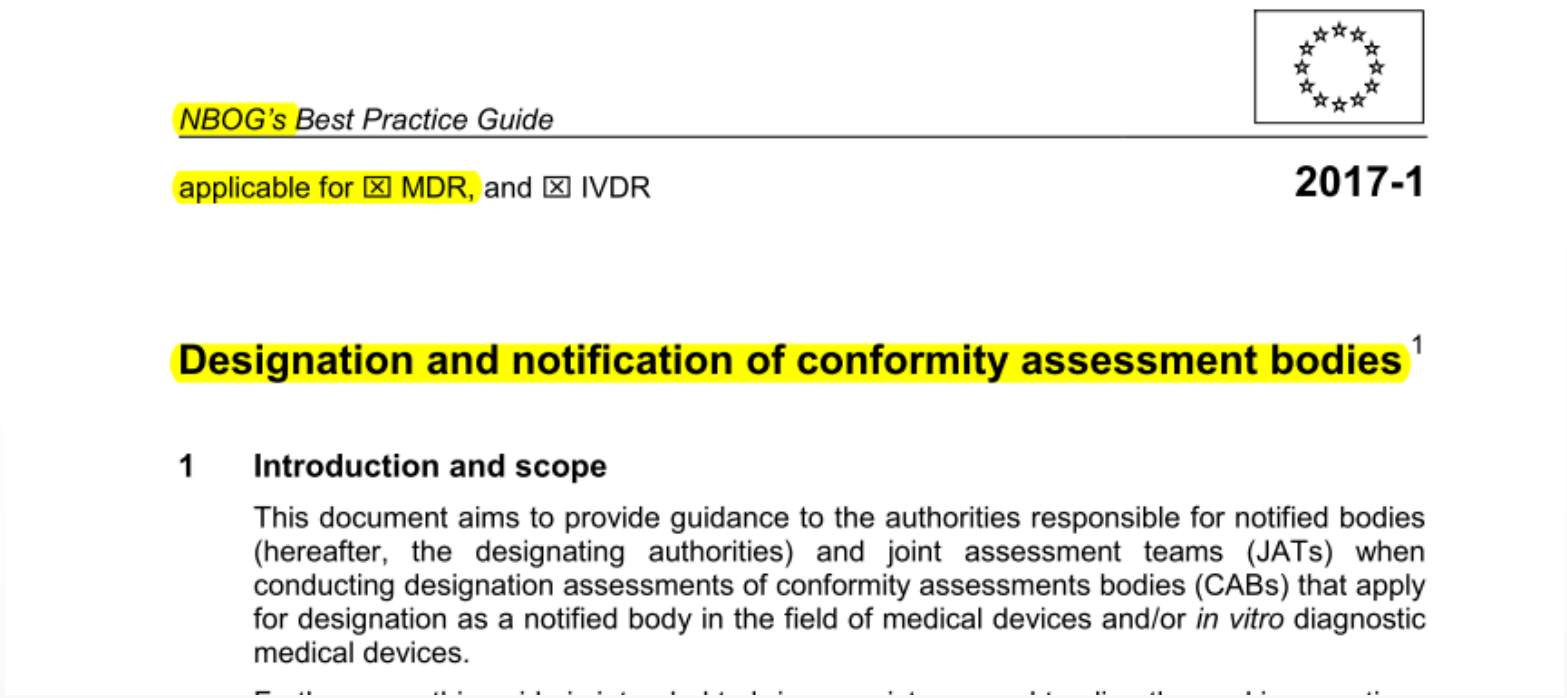
LSA2018

Lübeck, 4 July 2018

Agenda

- **Designation-Time Line: best and worst case**
- **Transfer to the MDR: best and real cases**
- **Impact on the Industrie: winner and loser**

Designation-Time Line



NBOG's Best Practice Guide

applicable for ☒ MDR, and ☒ IVDR

2017-1

Designation and notification of conformity assessment bodies[1]

1 Introduction and scope

This document aims to provide guidance to the authorities responsible for notified bodies (hereafter, the designating authorities) and joint assessment teams (JATs) when conducting designation assessments of conformity assessments bodies (CABs) that apply for designation as a notified body in the field of medical devices and/or *in vitro* diagnostic medical devices.

NBOG: Notified Body Operations Group

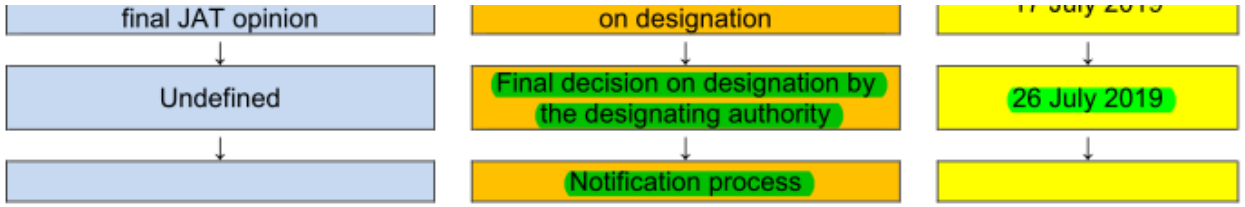
(Members are: EU Commission and Designating/Competent Authorities)

Designation-Time Line

Annex 1: Flowchart of activities and times

Tentative time-line	Activity	Tentative calendar for existing notified bodies (see section 2.1)
18 months in advance of repeal of relevant Directive	Application sent to the designating authority from the CAB	27 November 2017
anticipated on-site assessment	designating authority	
On-site assessment	In accordance with the agreed assessment plan	10 September 2018
Last day of the on-site assessment	Designating authority list of non-compliances and summary of the JAT assessment to be presented at the closing meeting	14 September 2018
Timeframe defined by the	CAB's submission of the CAPA	September/October

Designation-Time Line



<u>Original plan from NBOG (best case):</u>

- **first Notified Bodies in summer 2019**
- **after ca. 2/3 of the 3 years transitional period**

Designation-Time Line

Actual estimate:

- **first Notified Bodies in 1Q2019**

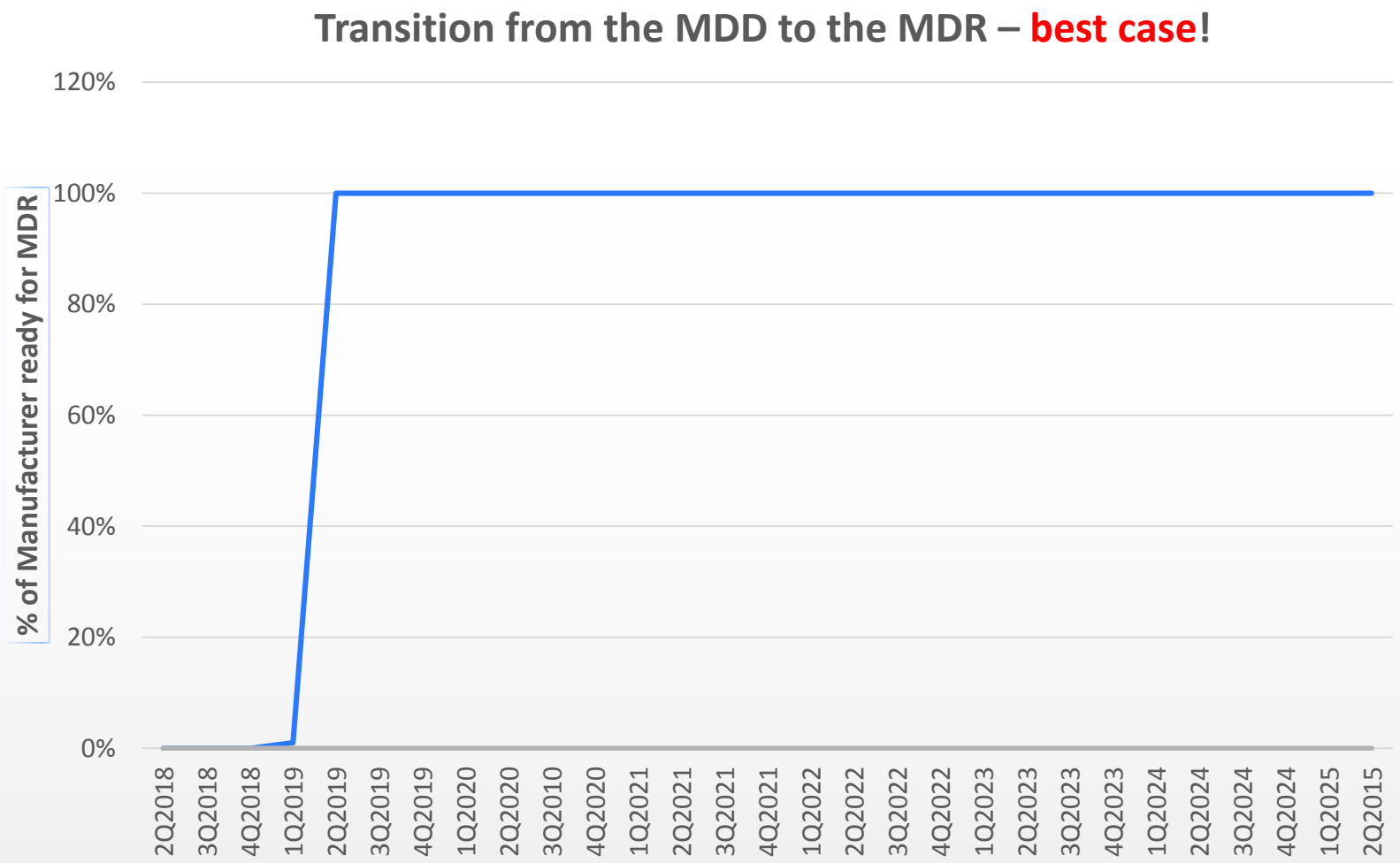
Worst cases:

- **Notified Body designated NOT before 05/2020**
- **Notified Body designated with a limited scope**
- **Notified Body not designated**
- **Notified Body did not apply (late decision)**

Transfer to the MDR – best case

- **Industrie is ready when Notified Body receives designation**

Transfer to the MDR – best case



Transfer to the MDR – best case

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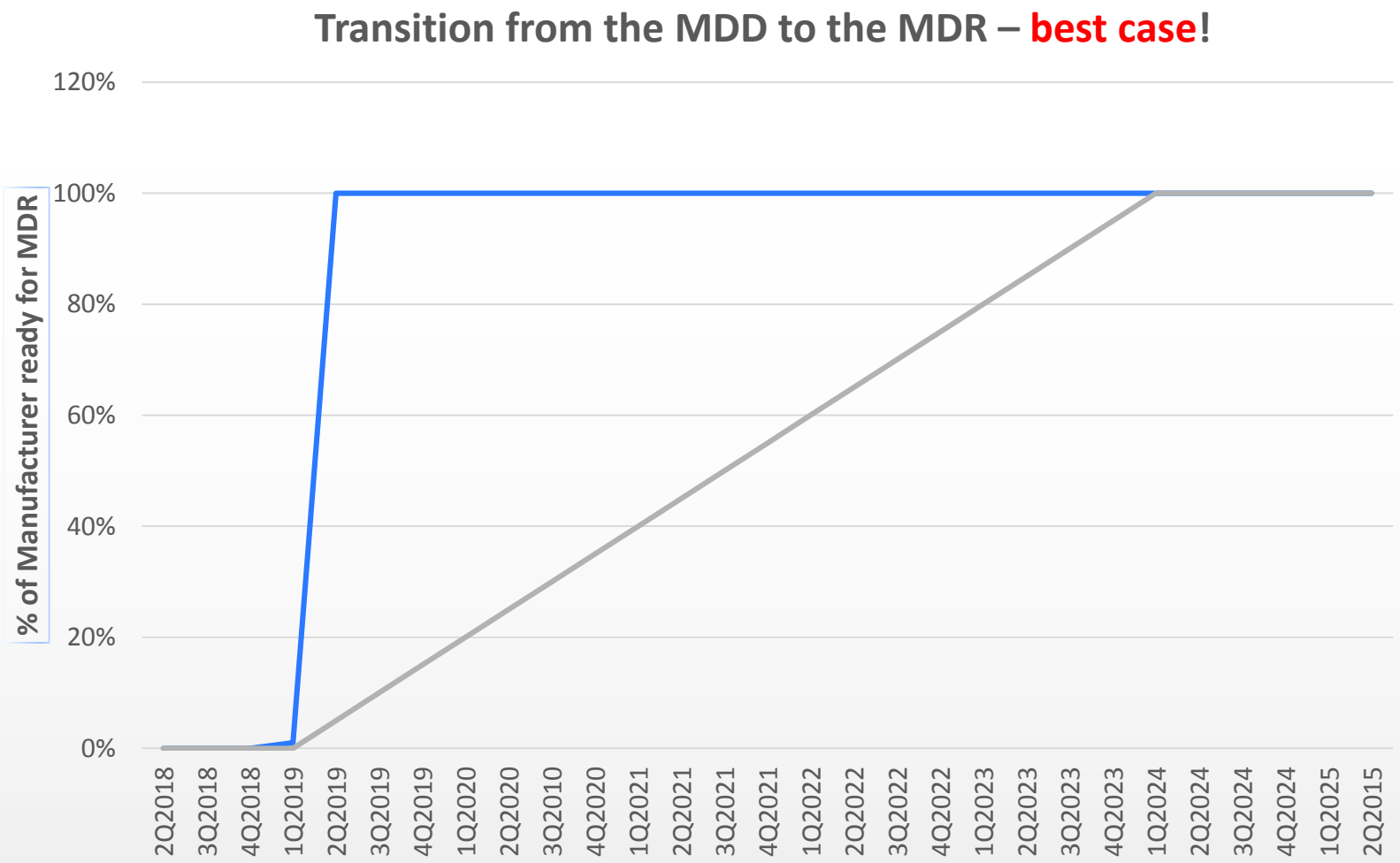
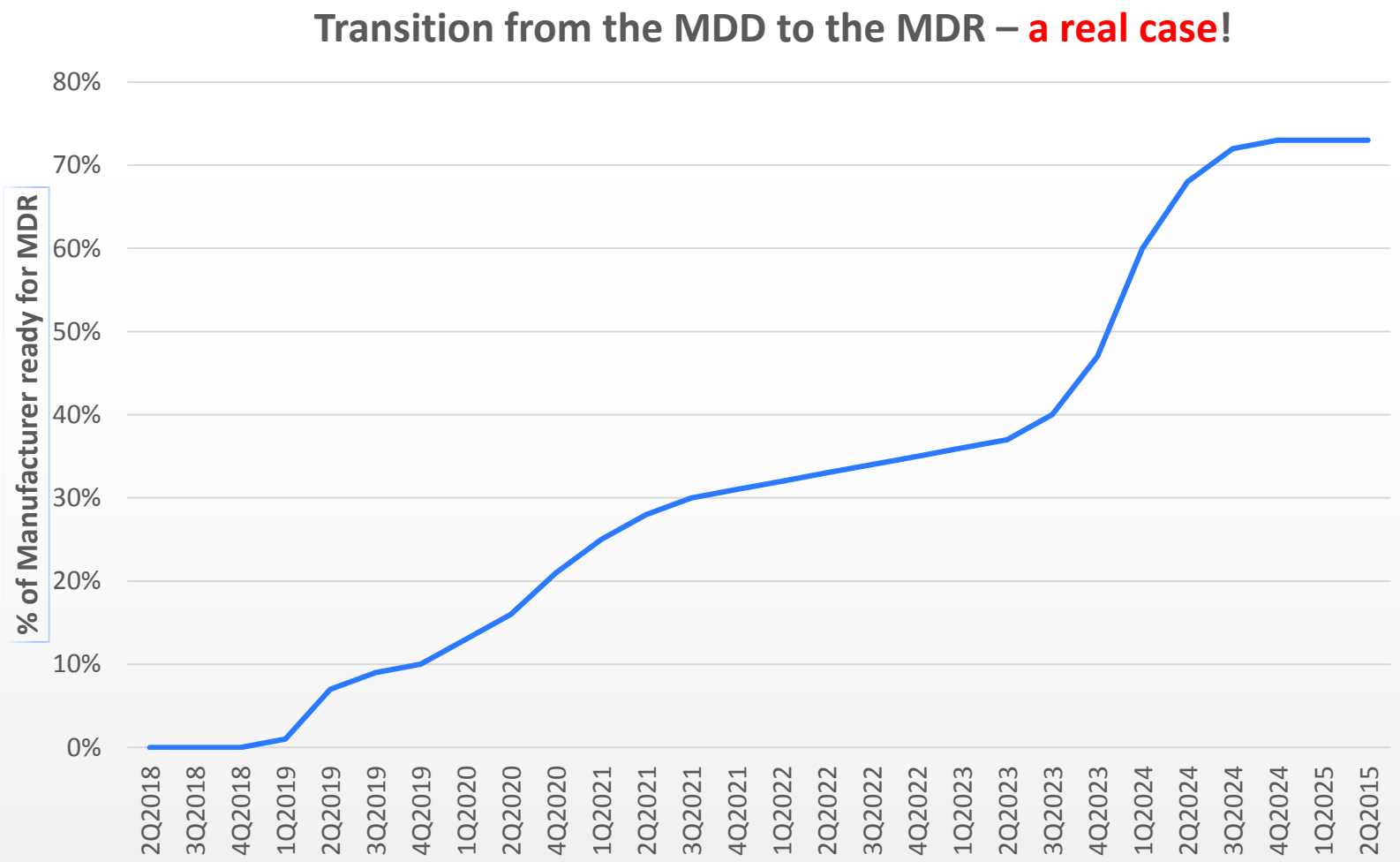


Transfer to the MDR – best case

- **but: each transfer is an „initial certification plus“**
- **Notified Body needs >10% more resources, to finalize the transfer process in 4 to 5 years!**

Transfer to the MDR – real case

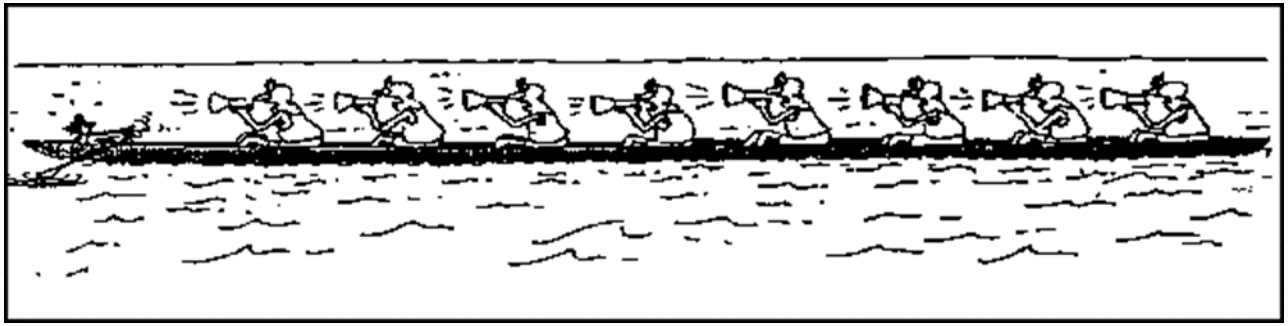


Transfer to the MDR – real case

- **Transfer of „Early Birds“ (ready in 2019) and „In-time Arriver“ (ready in 2020) is possible until 05/2024**
- **Transfer of „Too-late Arriver“ until.....**
- **Estimate, that > 20% of manufacturers will give-up**

Transfer to the MDR – real case

Working relationship between „Too-late Arriver“ and Notified Body:



• Impact on the Industrie: winner and loser

What about ....

- **Manufacturers who must change Notified Body?**
  - late designation
  - reduced scope
  - not designated
  - Brexit
- **Manufacturers of products in class I reprocessing?**
- **Manufacturers of products without an intended medical purpose?**

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