

Combining Patient Centric Drug Product Design & Packaging Engineering for successful therapy management

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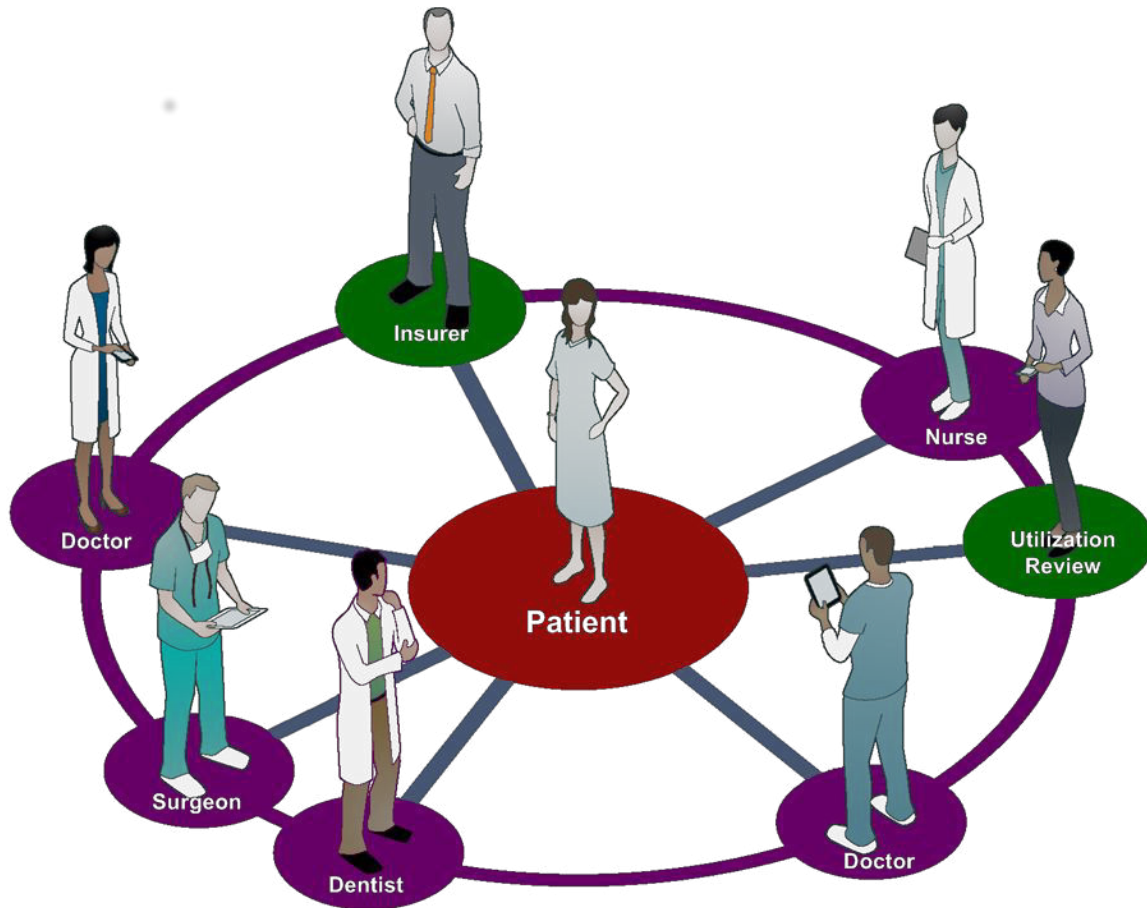


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The Patient Centric model in healthcare provision



- Patients are actively *involved* from early phase drug product development.
- Design and supply of drug products that *meets* the specific needs of patients.
- Individual preferences, values, and beliefs are *accountable* for selecting and designing appropriate therapeutic choices.
- Direct *interaction* with professionals to navigate the decision-making process and tailor their healthcare provision.

Patient Centric model implementation in healthcare

“You can’t deliver tomorrow’s innovation if you’re still using yesterday’s business models.”



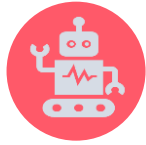
Patient-centric healthcare will accelerate while pharmaceutical companies deploy digital technology.

Consumer industry.....

- End user is involved ***very early*** into the development process of a product.
- Consumer market research (“clinical trials”)



Appropriateness



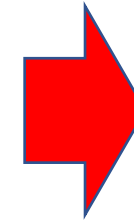
Use



Perception

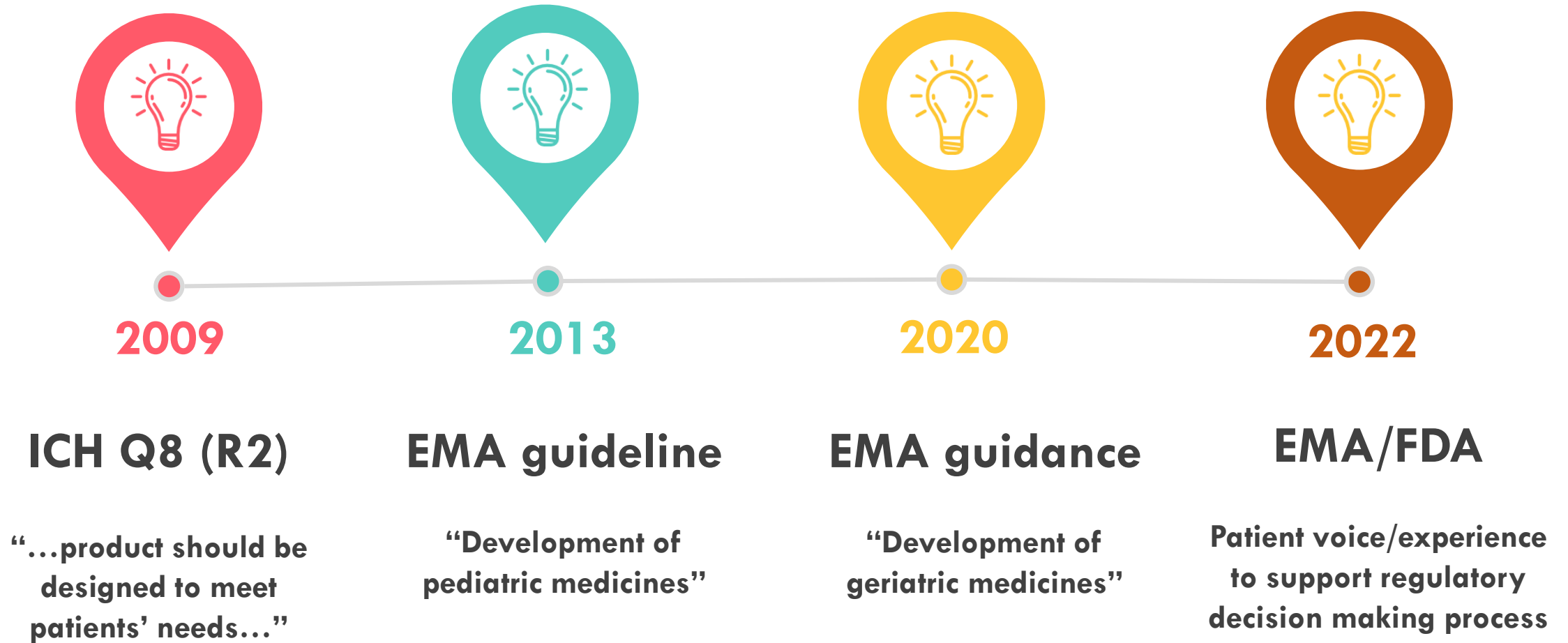


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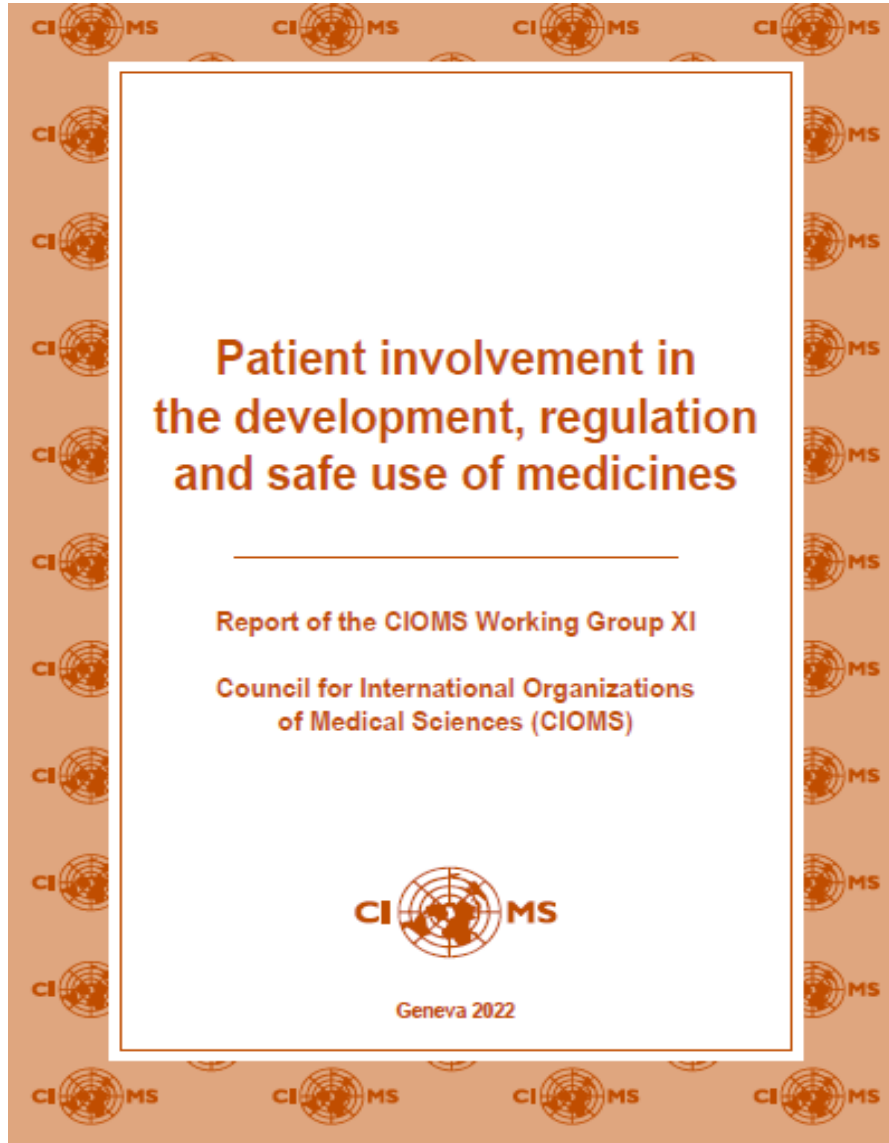


2021

Patient centric regulatory evolution



Patient centric regulatory evolution



Incorporating Patient's Voice in Product Development and Regulatory Decision Making



Patient-Focused Drug Development: Collecting

Guidance 1 (Final), June 2020

Patient-Focused Drug Development: Methods to

Guidance 2 (Final), February 2022

Patient-Focused Drug Development: Selecting

Guidance 3 (Draft), June 2022

Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints For Regulatory Decision-Making

Guidance 4 (Draft), April 2023

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

DRAFT GUIDANCE

<https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical>

COVID-19 pandemic **expedites digital** transformation

FDA NEWS RELEASE

FDA Takes Additional Steps to Advance Decentralized Clinical Trials

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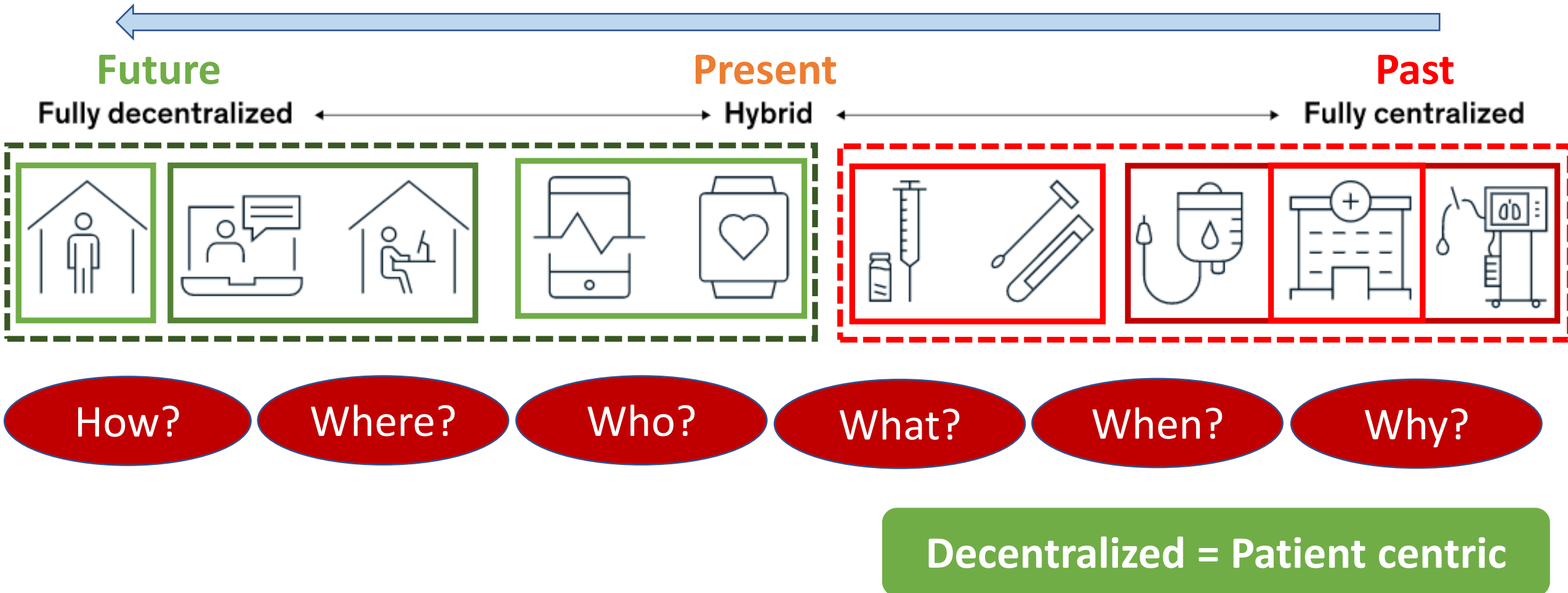
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Patient **centric** product design = **Decentralized** clinical trials

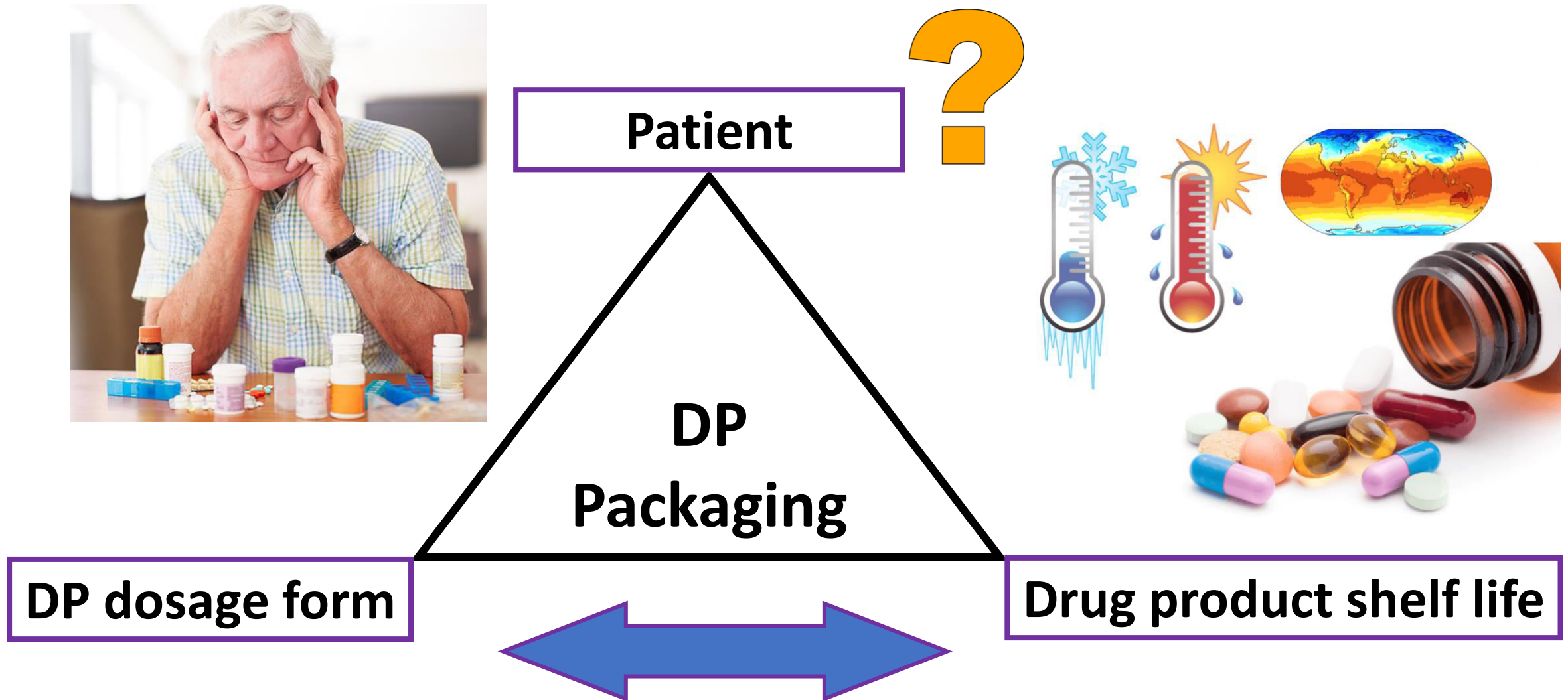
“There’s no place like home...”



Just a TV show or the simple **reality**?



Drug Product (DP) & Packaging Engineering



Poor packaging design can impact patient outcome

Visual Acuity

Handling / Grip / Dexterity

Objective 1- Estimate the prevalence of difficulty associated with the packaging of medications within the prehospital context within the previous 12 months of work

Difficulty <i>identifying</i> a medication 359 respondents indicate difficulty identifying a medication within the past 12 months (21.1%)		Difficulty <i>opening</i> a medication 349 respondents indicate difficulty opening a medication within the past 12 months (20.5%)	
Reasons for difficulty	n (% of total respondents; % of those reporting this difficulty with this product category)	Reasons for difficulty	n (% of total respondents; % of respondents reporting this difficulty with this product category)
Lack of transparency made product identification difficult	47 (2.8; 13.1)	Too small of an area to grip	125 (7.3; 35.8)
Crowded label	189 (11.1; 52.6)	Material meant to separate stuck together	116 (6.8; 33.2)
Small text	238 (14.0; 66.3)	Product required too much force to open	119 (7.0; 34.1)
Similar packaging different products	246 (14.5; 68.5)	Product required two hands to open	172 (10.1; 49.3)
Confusing names	55 (3.2; 15.3)	Unfamiliar with product packaging	60 (3.5; 17.2)
Dark conditions	117 (6.9; 32.6)	Packaging directions for opening were not clear	45 (2.6; 12.9)

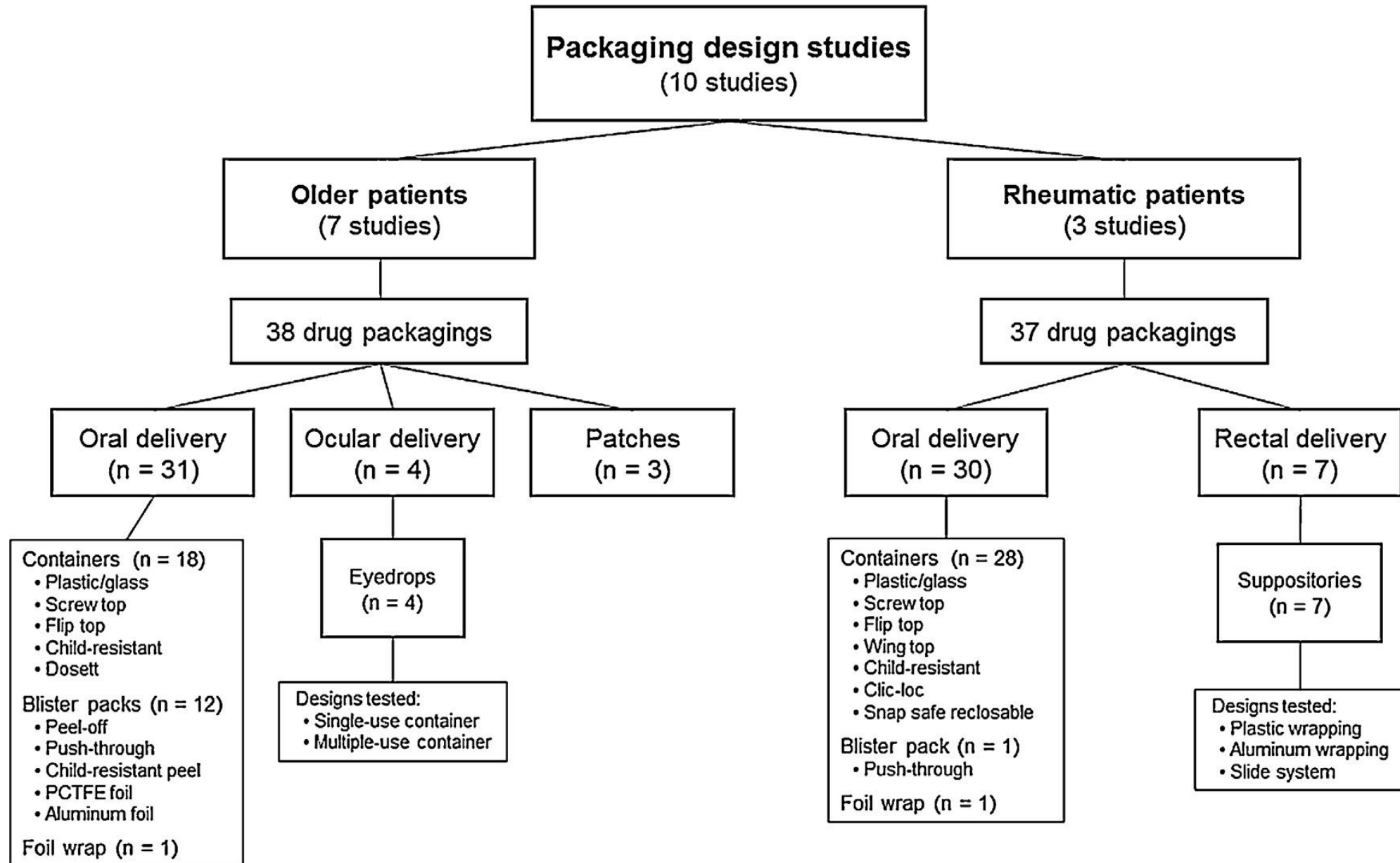
Objective 2- Investigate the coping strategies employed when difficulties occur with the packaging of medications

Coping strategies		Coping strategies	
Flashlight	211 (12.4; 58.8)	Knife	99 (5.8; 28.4)
Touch/feel	26 (1.5; 7.2)	Scissors	189 (11.1; 54.2)
Changed location of product within container, bag or ambulance	174 (10.2 48.5)	Teeth	103 (6.1; 29.5)
		Pen	76 (4.5; 21.8)
		Partner Assist	172 (10.1; 49.3)

Objective 3- Begin to quantify the potential impacts on care associated with difficulties with the packaging of medications

Difficulty resulted in negative patient outcome	20 (1.2; 5.6)	Difficulty resulted in negative patient outcome	32 (1.9; 9.2)
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Packaging Engineering: clinical evidence?







Packaging Engineering: clinical evidence?

Table 4

Publications on packaging design included the review.

	Authors	Research focus	Conclusions
Older patients	Atkin et al., 1994	Ability to handle standard medication packages	Packaging designs significantly impede access to medication
	Braun-Münker and Ecker, 2015	Influence of transparency and tablet/cavity size ratio on patients' handling two different blister materials	Limited movement and shifting space of the dosage form in the blister packaging was the most important factor for fast opening and patient satisfaction
	Dietlein et al., 2008	Ability to apply eyedrops from a single-use container versus standard container	Problems in self-administering eyedrops from single-use containers. Correlation to container size and training administration
	Keram and Williams, 1988	Quantitative comparison of the difficulty experienced when opening different medication container designs	Ability to open different types of child-resistant containers is variable (30% could not open). Large containers are preferred
	Mühlfeld et al., 2012	Relationship between blister pack designs and utilization problems	Opening force and opening mechanism can impact the usability of blister packs
	Nikolaus et al., 1996	To measure the prevalence of difficulty in opening and removing tablets from a range of common medicine containers	A high rate of failure in opening medication containers was seen. "Push and turn" bottles could not be opened by 2/3 of all tested subjects
Rheumatic patients	Parkkari et al., 2010	Handling of unit-dose pipettes in comparison to conventional eye drop bottles	Polyethylene unit-dose pipettes were at least as easy to handle as conventional eye drop bottles
	Le Gallez et al., 1984	Ability to handle different tablet containers	Flip off tops, tops with long threads requiring many turns, small and glass containers were unfavorable
	Lisberg et al., 1983	Ability to open a range of reclosable tablet containers and unit dose packs	Child-resistant containers, especially the "clic-loc" type, and smaller containers were less easy to open
	Verheggen-Laming et al., 1988	Difficulties involved in removing suppositories from the package	Patients have problems in opening suppository packages

Packaging Engineering: patient-centric considerations

Packaging design	Negative patient outcomes	Packaging design	Negative patient outcomes
Tablet containers 	<ol style="list-style-type: none"> Opening mechanism: <ul style="list-style-type: none"> Child-resistant Clic-Loc® Flip-off tops Push-and-turn Long threads / N° of turns Smaller container sizes Glass containers 	Blister packs 	<ol style="list-style-type: none"> Opening mechanism: <ul style="list-style-type: none"> Peel-push Force required Smaller tablet/cavity ratios Poor transparency
Packaging design	Negative patient outcomes	Packaging design	Negative patient outcomes
Suppositories 	<ol style="list-style-type: none"> Packaging type/material 	Eye drops 	<ol style="list-style-type: none"> Single-use containers Smaller container sizes Polyethylene pipettes

TaBlitz – Real-time 3D tablet & packaging design

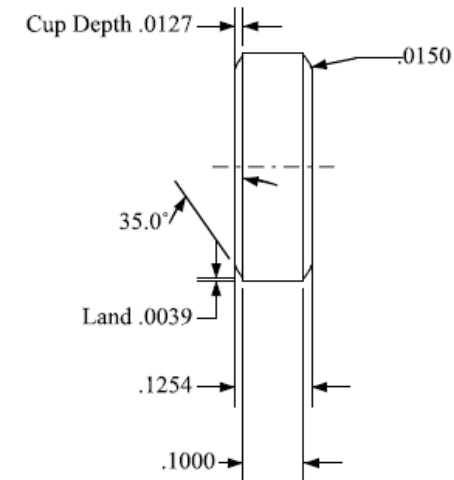
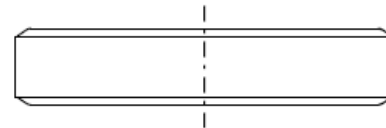
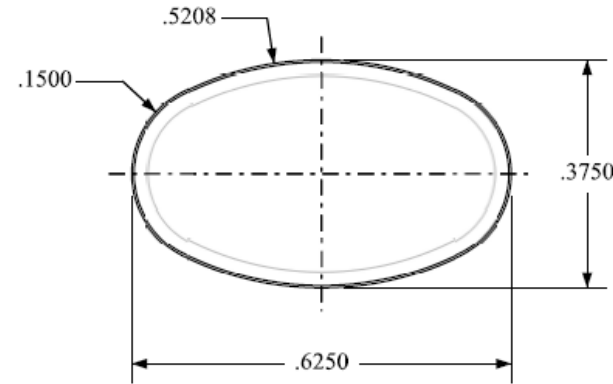
<https://www.tablitz.app/>

- **TaBlitz** produces an entire data packet including **2D tablet drawings** which provide **real-time information** required for blister & bottle packaging design.


TaBlitz – Real-time 3D tablet design & packaging

<https://www.tablitz.app/>

Shape: Oval
US metrics (in)



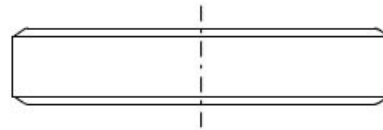
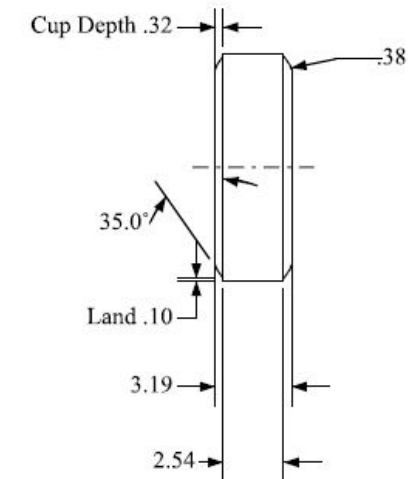
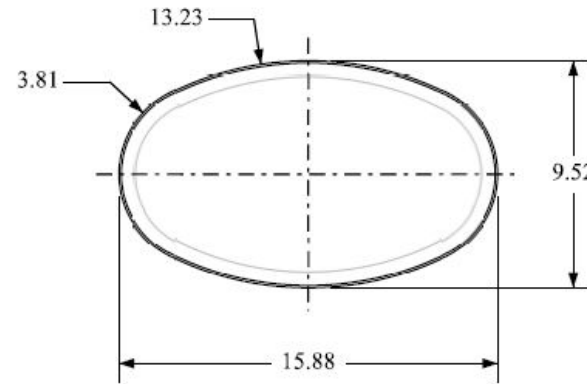
Scale: 4:1

Mass Properties		Tablet Type	Cup Type
Tablet Vol.	Tablet SA	Oval	Flat Face Bevel Edge
.02281 in ³	.5156 in ²	Created By	Created Date
Weight	Density	Mike Ruch	9/5/2023 10:50:53 PM
436 mg	19100 mg/in ³	Company Name	
Cup Vol.	Cup SA	DevWorks Automation	
.00200 in ³	.1739 in ²		
Die Hole Info			
Perimeter	SA		
1.6153 in	.1880 in ²		


TaBlitz – Real-time 3D tablet design & packaging

<https://www.tablitz.app/>

Shape: Oval
EU metrics (mm)



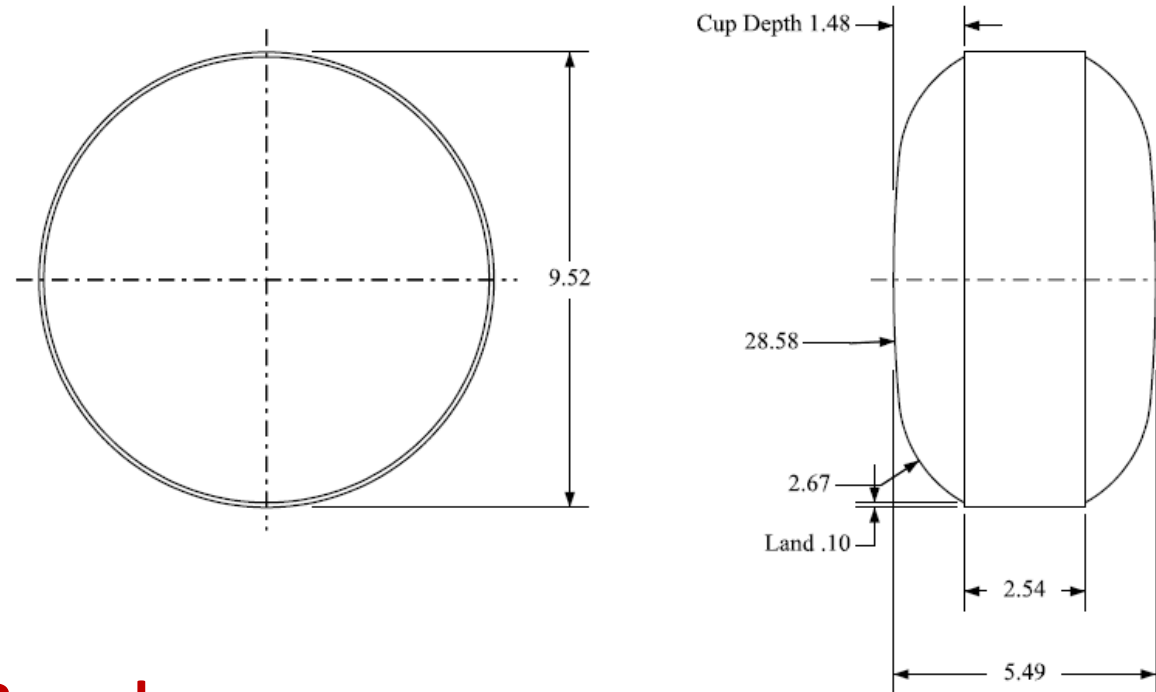
Scale: 4:1

Mass Properties		Tablet Type	Cup Type
Tablet Vol.	Tablet SA	Oval	Flat Face Bevel Edge
.02281 in ³	.5156 in ²	Created By	Created Date
Weight	Density	Mike Ruch	9/5/2023 10:50:53 PM
436 mg	19100 mg/in ³	Company Name	
Cup Vol.	Cup SA	DevWorks Automation	
.00200 in ³	.1739 in ²		
Die Hole Info			
Perimeter	SA		
41.03 mm	.1880 in ²		




TaBlitz – Real-time 3D tablet design & packaging

<https://www.tablitz.app/>



Shape: Round
EU metrics (mm)

Scale: 8:1

Mass Properties		Tablet Type	Cup Type
Tablet Vol.	Tablet SA	Round	Compound Cup
.01968 in ³	.3755 in ²	Created By	Created Date
Weight	Density	Mike Ruch	9/5/2023 10:50:53 PM
376 mg	19100 mg/in ³	Company Name	
Cup Vol.	Cup SA	DevWorks Automation	
.00432 in ³	.1266 in ²		
Die Hole Info			
Perimeter	SA		
29.92 mm	.1104 in ²		

TaBlitz – Real-time 3D tablet design & packaging

<https://www.tablitz.app/>

- TaBlitz produces an entire data packet including **2D tablet drawings** which provides **real-time information** required for blister & bottle packaging design.
- Pharmaceutical companies are on the **driver's seat** and no longer rely on tooling manufacturers to provide **tablet specs/drawings**.
- Additional benefits of TaBlitz proprietary software:
 - ✓ Real-time **2D/3D rendering**.
 - ✓ Intelligence-guided **tablet design** (can support strategic marketing).
 - ✓ **Cross-functional** design collaboration between functions/stakeholders.
 - ✓ Manufacturing-ready **design specifications** for **tooling** suppliers.





Questions?

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Design | Expert in Pharmaceutical Development, Clin...

