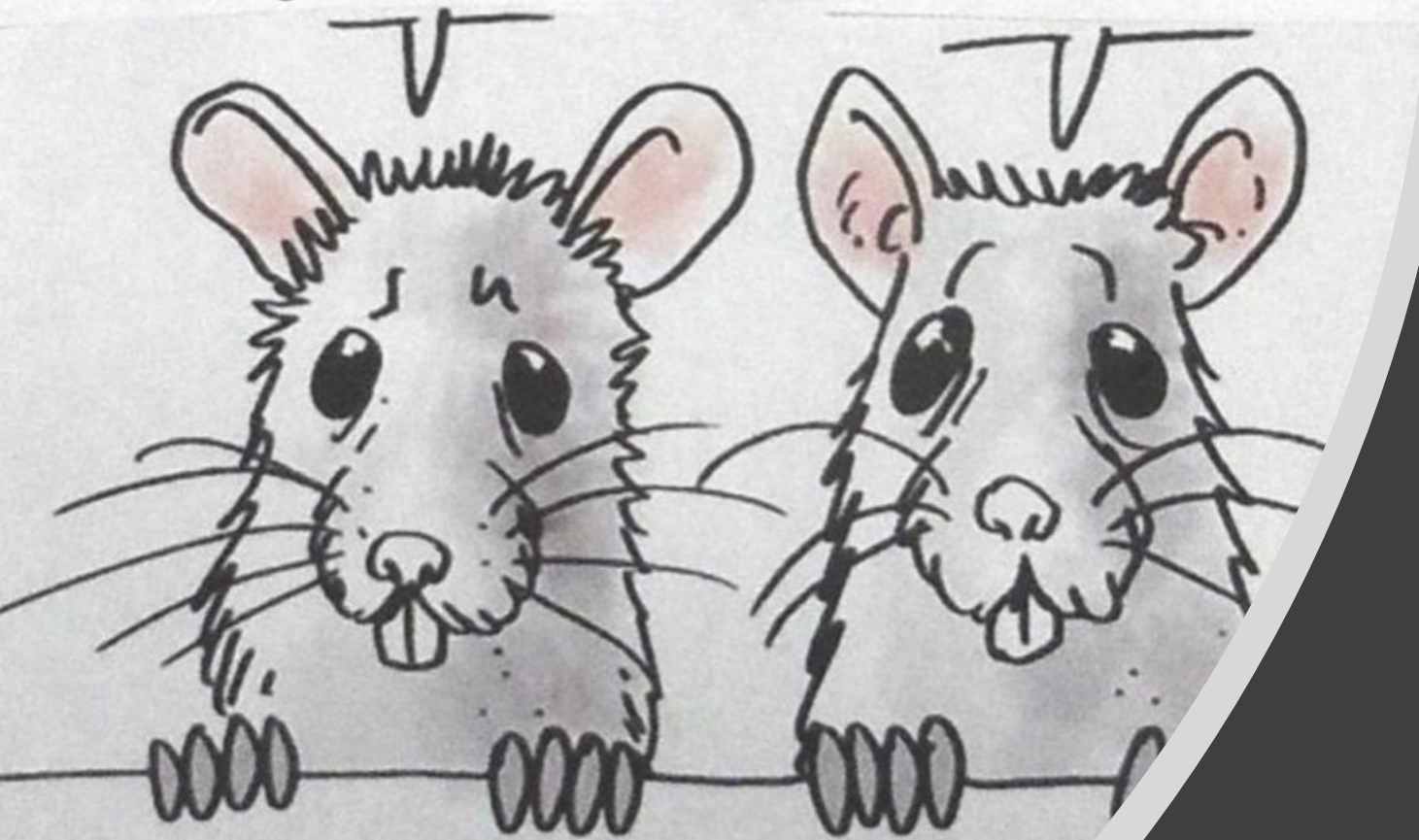


**Did they give you
the COVID vax
yet?**

**No, they're sti
testing it on
humans.**



Did Pfizer Do Any Safety Studies?

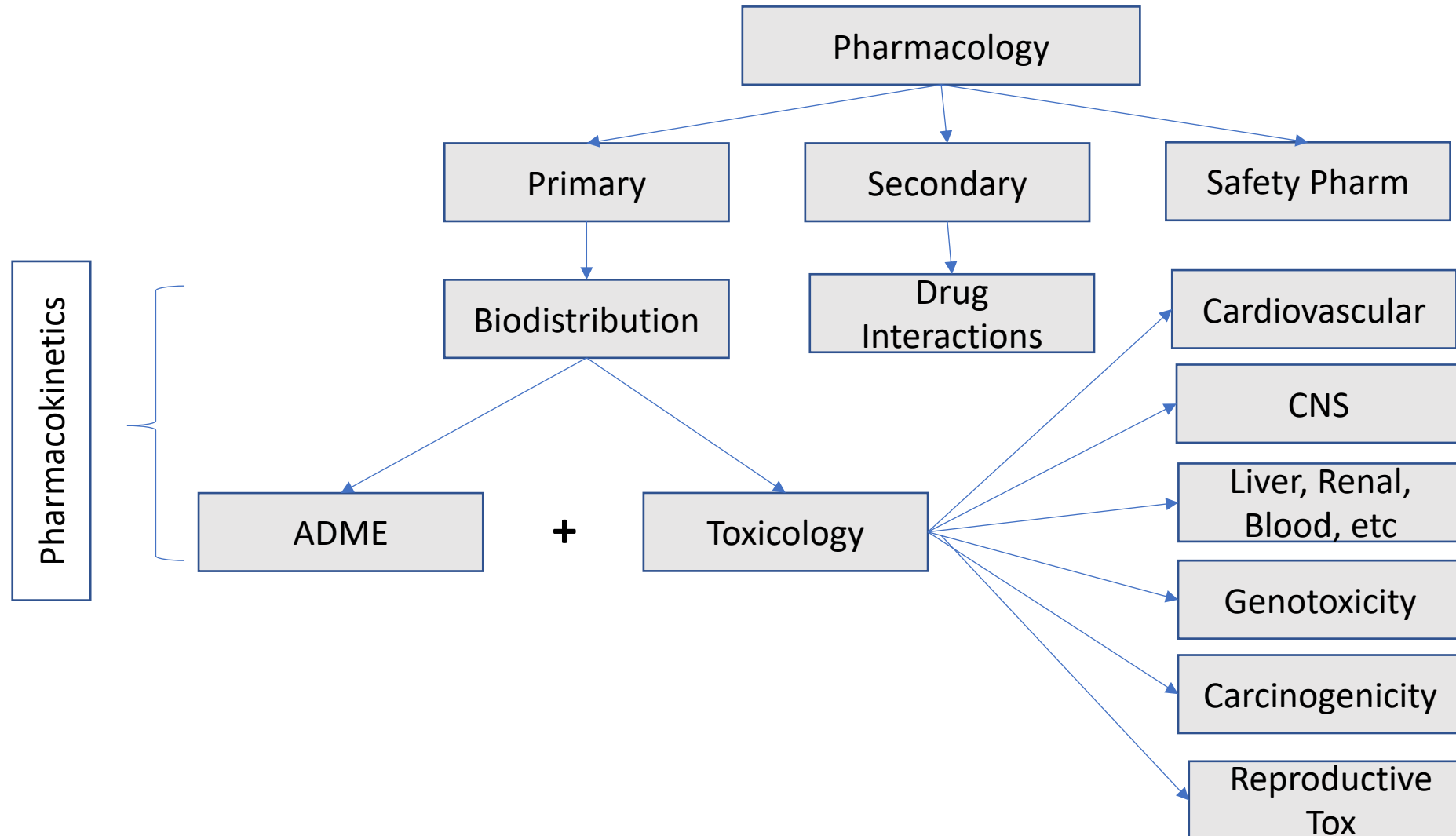
Pfizer's Non-Clinical Studies Used for FDA Review and Approval of Comirnaty Injection. Obtained by FOIA, March 2022

FDA and Pfizer **Knew** All Risks!

- FDA Guidance for Gene Therapy Products (June 2015) warns of severe risks with GTs:
 - Potential for multi-organ failure and death
 - Potential for tumors/cancer development
 - Potential for prolonged uncontrollable activity after single administration
 - Immunogenicity as a risk (autoimmunity)
 - Uncontrolled expression of genes
 - Migration of product to undesired organ systems
 - Possibility of shedding: excretion/secretion of viral particles that could be transmitted to other individuals
 - Studies in healthy volunteers are not generally advised due to potential severe risks

These products were UNAPPROVABLE by “normal” regulatory process. Crisis was the only way to push them on the market.

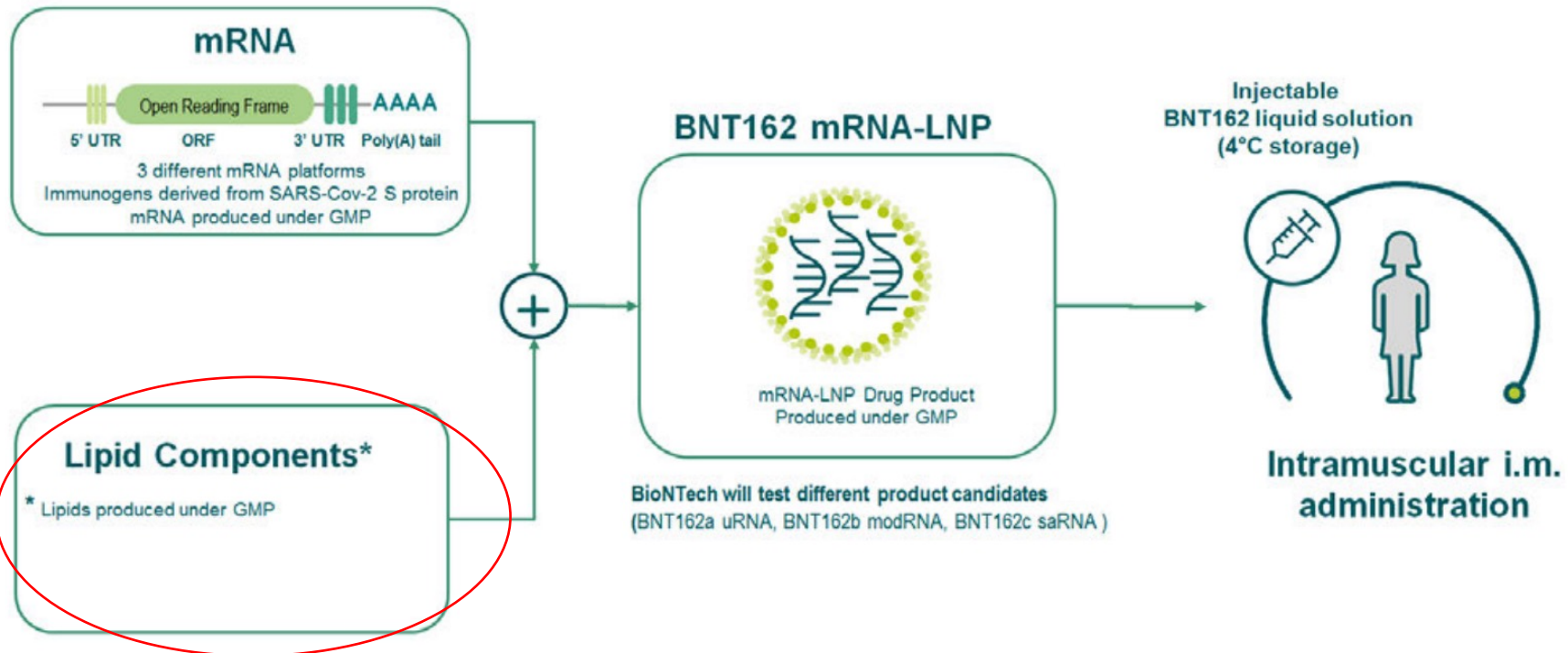
Summary of a Typical Non-Clinical Program for a New Drug



What is Pharmacokinetics?

- Pharmacokinetics, as a field, studies the movement of drugs/biologics throughout the body and the actions of the body on the drug:
 - Where in the body the substance is distributed?
 - In what concentrations?
 - What is the time course?
 - How is it metabolized?
 - How is it eliminated?
 - How controllable is it (over-/under-exposure)?
 - What is the therapeutic range: the lowest limit of therapeutic benefit and the highest limit of exposure that avoids adverse events?
 - Justification for dose selection?

Pfizer conducted pharmacokinetic studies for the nanoparticle delivery lipids ONLY



2.4.3. PHARMACOKINETICS

2.4.3.1. Brief Summary

Assessment of the ADME profile of BNT162b2 (BioNTech code number BNT162, Pfizer code number PF-07302048) included evaluating the PK and metabolism of two novel lipid excipients (ALC-0315 and ALC-0159) in the LNP and potential biodistribution of BNT162b2 using luciferase expression as a surrogate reporter. The luciferase reporter was used as it was a readily available reporter that has been widely used to develop an understanding of protein/organ expression (Chen et al, 2020; Elia et al, 2020; Fukuchi et al, 2020; Hassett et al, 2019; Truong et al, 2019; Barry et al, 2012; Jeon et al, 2006). An intravenous rat PK study, using LNPs with the identical lipid composition as BNT162b2, demonstrated that ALC-0315 and ALC-0159 distribute from the plasma to the liver. While there was no detectable excretion of either lipid in the urine, the percent of dose excreted unchanged in feces was ~1% for ALC-0315 and ~50% for ALC-0159.

The biodistribution of BNT162b2 was evaluated using luciferase expression as a surrogate reporter in BALB/c mice. Mice were administered a luciferase expressing modRNA formulated like BNT162b2, with the identical lipid composition. Luciferase expression was measured in vivo following luciferin application. Luciferase expression was identified at the injection site at 6 hours after injection and was not detected after 9 days. Expression in the liver was also present to a lesser extent at 6 hours after injection and was not detected by 48 hours after injection. The distribution was also examined in male and female Wistar Han rats using LNPs with a comparable lipid composition to BNT162b2 but with a surrogate luciferase RNA and containing trace amounts of radiolabeled [³H]-CHE, a

non-exchangeable, non-metabolizable lipid marker. The greatest mean concentration of LNP was found remaining in the injection site in both sexes. Total recovery (% of injected dose) of LNP outside the injection site was greatest in the liver and was much less in the spleen, adrenal glands, and ovaries.

The in vitro metabolism of ALC-0315 and ALC-0159 was evaluated in blood, liver microsomes, S9 fractions, and hepatocytes from mice, rats, monkeys, and humans. The in vivo metabolism was examined in rat plasma, urine, feces, and liver samples from the PK study. Metabolism of ALC-0315 and ALC-0159 appears to occur slowly in vitro and in vivo. ALC-0315 and ALC-0159 are metabolized by hydrolytic metabolism of the ester and amide functionalities, respectively, and this hydrolytic metabolism is observed across the species evaluated.

Pfizer, CDC and FDA lied repeatedly about “vaccine staying in the injection site”. The substance is clearly getting distributed into the liver, spleen, ovaries and other organs.

Yet, no safety pharmacology studies were done and therefore we have no knowledge of the safety margins!

In Study 20256434, female rats were administered 4 total IM doses of BNT162b2 (V9) 21 and 14 days prior to mating and on GD9 and GD20. Serum samples were collected from females prior to vaccine administration, just prior to mating (M0), at the end of gestation (GD21), and at the end of lactation (LD21) and offspring (fetuses on GD21 and pups on PND21). Sera were analyzed for SARS-CoV-2 neutralizing antibodies. After immunization, SARS-CoV-2 neutralizing titers were detected in all maternal females as well as in their offspring (fetuses and pups). SARS-CoV-2 neutralizing antibody titers were not observed in animals prior to vaccine administration or in saline-administered control animals.

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FDA-CBER-2021-4379-0000676

Obtained via FOIA by Judicial Watch, Inc.

BNT162b2
Module 2.4. Nonclinical Overview

2.4.2.2. Secondary Pharmacodynamics

No secondary pharmacodynamics studies were conducted with BNT162b2.

2.4.2.3. Safety Pharmacology

No safety pharmacology studies were conducted with BNT162b2 as they are not considered necessary for the development of vaccines according to the WHO guideline ([WHO, 2005](#)).

2.4.2.4. Pharmacodynamic Drug Interactions

Nonclinical studies evaluating pharmacodynamic drug interactions with BNT162b2 were not conducted as they are generally not considered necessary to support development and licensure of vaccine products for infectious diseases ([WHO, 2005](#)).

- mRNA injections do not meet the WHO 2005 definition of the vaccine.
- The more novel the technology the more stringent safety evaluation should be used (and were historically required by the FDA).
- FDA approves medicines in the US, not WHO. Yet, FDA did not push back on this nonsense claim.

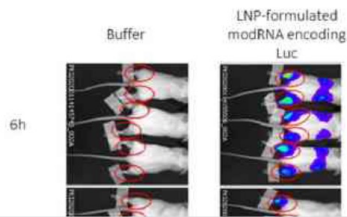
Pharmacokinetic studies have not been conducted with BNT162b2 and are generally not considered necessary to support the development and licensure of vaccine products for infectious diseases (WHO, 2005; WHO, 2014).

2.4.3.4. Distribution

In an in vivo study (R-20-0072; Tabulated Summary 2.6.5.5A), biodistribution was assessed using luciferase as a surrogate marker protein, with RNA encoding luciferase formulated like BNT162b2, with the identical lipid composition. The LNP-formulated luciferase-encoding modRNA was administered to BALB/c mice by IM injection of 1 µg each in the right and left hind leg (for a total of 2 µg). Using in vivo bioluminescence after injection of luciferin substrate, luciferase protein expression was detected at different timepoints at the site of injection and to a lesser extent, and more transiently, in the liver (Figure 2.4.3-2. Distribution to the liver is likely mediated by LNPs entering the blood stream. The luciferase expression at the injection sites dropped to background levels after 9 days. The repeat-dose toxicity study in rats showed no evidence of liver injury (Section 2.4.4.3).

The biodistribution of the antigen encoded by the RNA component of BNT162b2 is expected to be dependent on the LNP distribution and the results presented should be representative for the vaccine RNA platform, as the LNP-formulated luciferase-encoding modRNA had the same lipid composition.

Figure 2.4.3-2. Bioluminescence Emission in BALB/c Mice after IM Injection of an LNP Formulation of modRNA Encoding Luciferase



Pharmacokinetics of the Active Ingredient or full product WERE NOT STUDIED

Substituted the active ingredient with an irrelevant one (coding for luciferase, not spike protein) and claim it's "the same" as mRNA coding for spike!!!

Repeat: NEVER TESTED SPIKE CODING mRNA FOR BIODISTRIBUTION/SAFETY

Table 2 Mean Concentration of Total Radioactivity in Whole Blood, Plasma and Tissues Following Single Intramuscular Administration of [³H]-08-A01-C01 to Wistar Han Rats

Target Dose Level: 50 µg mRNA/Animal; 1.29 mg Total Lipid/Animal

Results expressed as µg lipid equiv/g (mL)

Sample	0.25 min		1 h		2 h		4 h		8 h		24 h		48 h	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Adipose tissue	0.040	*0.073	0.050	0.149	0.070	0.182	0.093	0.163	0.116	0.069	0.126	0.042	0.129	0.232
Adrenal glands	0.302	*0.240	0.580	2.388	1.206	4.232	2.569	3.206	6.387	7.218	19.948	7.595	21.476	14.942
Bladder	0.049	*0.033	0.095	0.165	0.137	0.155	0.227	0.106	0.211	0.085	0.323	0.171	0.340	0.389
Bone (femur)	0.126	0.056	0.148	0.241	0.235	0.296	0.335	0.217	0.502	0.177	0.504	0.180	0.520	0.854
Bone marrow (femur)	0.761	*0.196	0.910	1.010	1.136	1.337	1.557	0.915	2.397	1.274	3.579	1.405	3.690	3.851
Brain	0.073	*0.016	0.083	0.117	0.143	0.133	0.155	0.075	0.101	0.045	0.090	0.047	0.083	0.052
Eyes	0.014	*0.006	0.027	0.043	0.046	0.058	0.095	0.038	0.088	0.030	0.129	0.052	0.127	0.097
Heart	0.419	*0.144	0.631	1.426	1.122	1.682	1.049	0.925	1.189	0.391	0.583	0.318	0.672	0.420
Injection site	219.940	36.566	587.670	199.950	529.210	93.144	619.850	56.227	299.590	125.930	267.170	122.540	268.770	61.088
Kidneys	0.511	0.271	0.630	1.692	1.124	2.967	1.033	0.814	0.837	0.342	0.504	0.348	0.482	0.368
Large intestine	0.017	*0.008	0.031	0.065	0.080	0.106	0.350	0.224	0.690	0.608	1.741	0.466	1.426	1.249
Liver	1.151	0.323	4.006	5.244	9.574	12.370	18.525	14.569	27.916	25.172	23.360	15.119	18.164	30.411
Lung	0.737	0.247	0.845	1.574	1.594	2.074	1.772	1.222	1.674	0.628	1.316	0.762	1.288	0.898
Lymph node (man)	0.090	*0.038	0.154	0.223	0.217	0.362	0.424	0.391	0.695	0.372	0.744	0.363	0.820	0.633
Lymph node (mes)	0.052	*0.048	0.095	0.196	0.229	0.831	0.441	0.536	0.649	0.729	1.106	0.863	1.057	1.675
Muscle	*0.029	0.012	0.039	0.082	0.067	0.100	0.075	0.130	0.101	0.091	0.098	0.092	0.280	0.104
Ovaries (females)	-	*0.104	-	1.339	-	1.638	-	2.341	-	3.088	-	5.240	-	12.261
Pancreas	0.125	0.037	0.153	0.261	0.423	0.404	0.361	0.398	0.349	0.239	0.396	0.320	0.587	0.611
Pituitary gland	0.537	*0.141	0.446	0.844	0.781	0.955	1.249	0.458	0.669	0.141	0.656	0.300	0.543	0.845
Prostate (males)	0.061	-	0.091	-	0.128	-	0.157	-	0.150	-	0.183	-	0.170	-
Salivary glands	0.114	*0.054	0.148	0.237	0.214	0.295	0.270	0.169	0.176	0.094	0.243	0.096	0.297	0.231
Skin	*0.016	0.010	0.028	0.387	0.054	0.263	0.085	0.204	0.122	0.116	0.195	0.118	0.209	0.297

The substance is clearly getting distributed into the adrenal glands, liver, spleen, ovaries, bone marrow. Lymph nodes and all other organs.

Concentration in the liver, spleen and ovaries for females is still increasing when the study is stopped.

Sample	0.25 min		1 h		2 h		4 h		8 h		24 h		48 h	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Small intestine	0.038	*0.021	0.194	0.247	0.471	0.481	0.919	0.838	1.525	1.033	1.878	0.726	1.630	1.314
Spinal cord	0.061	*0.024	0.072	0.122	0.166	0.172	0.375	0.124	0.168	0.044	0.121	0.048	0.162	0.062
Spleen	0.354	*0.313	2.140	2.801	5.255	10.213	8.945	11.646	24.434	19.747	22.819	17.341	19.550	27.155
Stomach	0.018	*0.015	0.039	0.091	0.104	0.126	0.186	0.101	0.410	0.126	0.222	0.081	0.235	0.195
Testes (males)	0.031	-	0.042	-	0.079	-	0.129	-	0.146	-	0.304	-	0.320	-
Thymus	0.106	*0.069	0.187	0.298	0.220	0.459	0.461	0.209	0.292	0.100	0.255	0.159	0.296	0.366
Thyroid	0.217	*0.093	0.391	0.680	0.575	1.109	1.097	0.604	0.781	0.307	0.820	0.335	1.344	0.655
Uterus (females)	-	*0.043	-	0.203	-	0.305	-	0.140	-	0.287	-	0.289	-	0.456
Whole Blood	3.003	0.936	2.809	5.928	4.028	6.773	3.400	2.698	2.000	0.628	1.274	0.544	0.535	0.305
Plasma	6.035	1.894	5.379	10.884	8.714	9.091	8.755	4.251	3.573	1.147	2.621	0.945	1.085	0.524
Blood:plasma ratio	0.48	1.15	0.49	0.54	0.46	0.64	0.42	0.60	0.56	0.55	0.49	0.57	0.50	0.58

Even small amounts of mRNA/spike protein expressed in vital organs can have unknown, possibly catastrophic effects.

*=Mean includes results calculated from data less than 30 cpm above background

2.4.3.3.2. Single-Dose Pharmacokinetics

An intravenous rat PK study (PF-07302048_06Jul20_072424; Tabulated Summary 2.6.5.3) was performed using LNPs containing surrogate luciferase RNA, with the identical lipid composition as BNT162b2. This study was conducted to explore the disposition of ALC-0315 and ALC-0159 that had reached the systemic circulation following IM administration; thus, the IV route was felt to be appropriate. The findings are depicted in Table 2.4.3-1 and Figure 2.4.3-1.

Table 2.4.3-1. PK of ALC-0315 and ALC-0159 in Wistar Han Rats After IV Administration of LNPs Containing Surrogate Luciferase RNA at 1 mg/kg

Analyte	Dose of Analyte (mg/kg)	Gender /N	t _{1/2} (h)	AUC _{inf} (µg·h/mL)	AUC _{last} (µg·h/mL)	Estimated fraction of dose distributed to liver (%) ^a
ALC-0315	15.3	Male/3 ^b	139	1030	1020	60
ALC-0159	1.96	Male/3 ^b	72.7	99.2	98.6	20

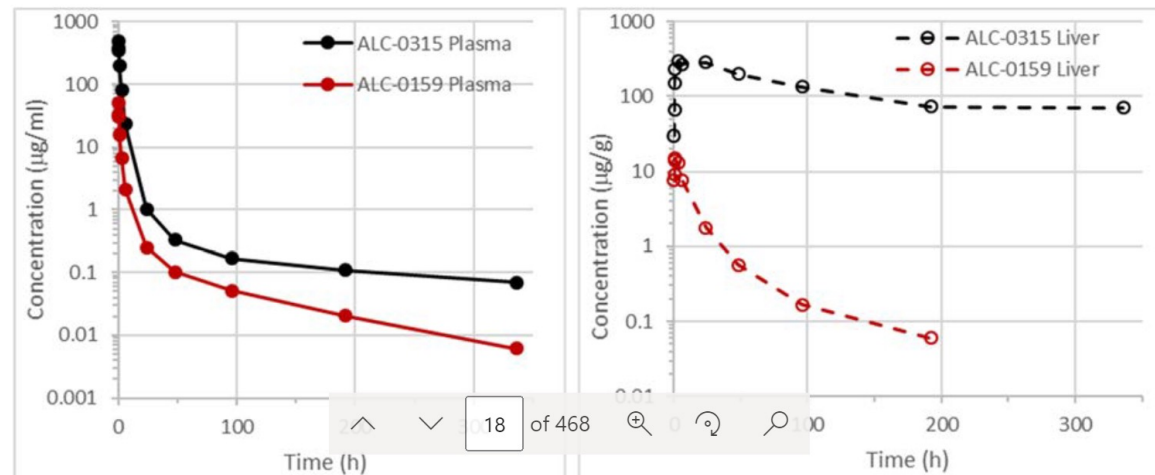
a. Calculated as highest mean amount in the liver (µg)/total mean dose (µg) of ALC-0315 or ALC-0159.

b. 3 animals per timepoint; non-serial sampling.

Pfizer was expecting the injections to be reaching blood stream directly.

The excipients are getting to the liver in large quantities, yet there are no safety pharmacology, or any follow up studies on studies of hepatotoxicity!

Figure 2.4.3-1. Plasma and Liver Concentrations of ALC-0315 and ALC-0159 in Wistar Han Rats After IV Administration of LNPs Containing Surrogate Luciferase RNA at 1 mg/kg



ALC-0315: no decrease of concentration at 300h after injection. No data on if/when it was cleared from liver.

Summary of PK for PfizerC19 Injection:

- Pfizer chose to study PK/distribution for lipid delivery vehicle only:
 - Not all studies contained the same formulations of lipids
 - Did not study how the spike protein would be distributed and expressed, and what toxicities it might cause
 - Did not fully characterize time course of distribution, esp. for females
 - Demonstrated high concentrations of lipid nanoparticles (which would be carrying mRNA and expressing toxic spike protein in major organs) and then chose not to study it any further.
- Regulators did not question any of this!

Toxicology: Study of harmful effects of substances

Toxicology – Studies with BNT162b2 variants					
38166	Repeat-dose toxicity	Wistar Han Rats	BNT162b2 (V8)	100 µg	Section 2.4.4.3
20GR142	Repeat-dose toxicity	Wistar Han Rats	BNT162b2 (V9)	30 µg	Section 2.4.4.3
20256434	Development and Reproductive Toxicity	Wistar Han Rats	BNT162b2 (V9)	30 µg	Section 2.4.4.6

Different version of product

Non-GLP study

Only 1 study was done for the “correct” version and in a validated setting, let’s review...

Pfizer Claims “No Systemic Effects” in a Rat Toxicity Study

- 20% decrease in food consumption, and increase in body temperature (fever), weight loss
- Clinical pathology changes consistent with inflammation
- Increase in lab parameters, still increasing at the time the study was stopped!
 - 3X WBC, 7X neutrophils, 3X monocytes, 13X LUC
 - 2.5X Fibrinogen, 39X alpha1-acid Glycoprotein, 71X alpha2 Macroglobulin
- Increase in spleen weight 1.5X
- Enlarged draining lymph nodes (not recovered at the end of study)
- Pathology findings in lymph nodes, liver, spleen, bone marrow noted and ignored

Pfizer waived all of this off as “immune system is reacting, and it will be ok”.

What is Safety Pharmacology?

- Safety pharmacology investigates potential undesirable pharmacodynamic effects of **new medicines** on physiological functions in relation to exposure in the therapeutic range and above.
- Primary organ systems (so-called core battery systems) are:
 - Central Nervous System
 - Cardiovascular System
 - Respiratory System
- Secondary organ systems of interest are:
 - Gastrointestinal System
 - Renal System
 - Other systems if exposure detected/known
- Safety pharmacology studies are required to be completed prior to human exposure (i.e., Phase I clinical trials), and regulatory guidance is provided in ICH S7A and other documents.
- **Safety pharmacology studies are required for all components of the new pharmaceutical product. They are particularly critical for the novel proprietary and undisclosed excipients used by Pfizer – ALC-0315 and ALC-0159.**

Pfizer declared Genotoxicity and Carcinogenicity as not applicable based on WHO Guidelines

2.4.4.4. Genotoxicity

No genotoxicity studies are planned for BNT162b2 as the components of the vaccine construct are lipids and RNA and are not expected to have genotoxic potential (WHO, 2005).

2.4.4.5. Carcinogenicity

Carcinogenicity studies with BNT162b2 have not been conducted as the components of the vaccine construct are lipids and RNA and are not expected to have carcinogenic or tumorigenic potential. Carcinogenicity testing is generally not considered necessary to support the development and licensure of vaccine products for infectious diseases (WHO, 2005).

Based on the recent study* it was demonstrated that mRNA does incorporate into DNA via reverse transcription.

**Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line*

Markus Aldén et al, Department of Clinical Sciences, Lund University, 20502 Malmö, Sweden

What do WHO Guidelines from 2005 say?

- 4.2.4 Safety pharmacology The purpose of safety pharmacology is to investigate the effects of the candidate vaccine on vital functions. If data from nonclinical and/or human clinical studies suggest that the vaccine (e.g. one based on specific toxoids) may affect physiological functions (e.g. central nervous system, respiratory, cardiovascular and renal functions) other than those of the immune system, safety pharmacology studies should be incorporated into the toxicity assessment. Useful information on this topic can be found in the Note for Guidance on safety pharmacology studies for human pharmaceuticals.

What do WHO Guidelines say (cont)?

- 4.2.3 Genotoxicity and carcinogenicity studies Genotoxicity studies are normally not needed for the final vaccine formulation. However, they may be required for particular vaccine components such as novel adjuvants and additives. If needed, the in vitro tests for mutations and chromosomal damage should be done prior to first human exposure. The full battery of tests for genotoxicity may be performed in parallel with clinical trials.
- Carcinogenicity studies are not required for vaccine antigens. However, they may be required for particular vaccine components such as novel adjuvants and additives.

These studies are required for novel products. At a minimum, they are required for novel, proprietary and undisclosed excipients ALC-0315 and ALC-0159.

Pfizer collected NO cardiovascular safety data in Preclinical Studies

- “Cardiovascular” is not mentioned in the entire package, even once (450 pages).
- “Cardiac” mentioned 2 times when describing sampling tissues in rat studies. No assessment of impact on any cardiac function was done.
- Pfizer have not done (or not reported) any information about possible impact on cardiac function and simply told the FDA that cardiovascular safety evaluations do not apply to their product.
- **Absence of evidence is not evidence of absence!**

Cardiovascular deaths have exploded right after the mass vaccination rollout (2 months of data, Feb 2021)

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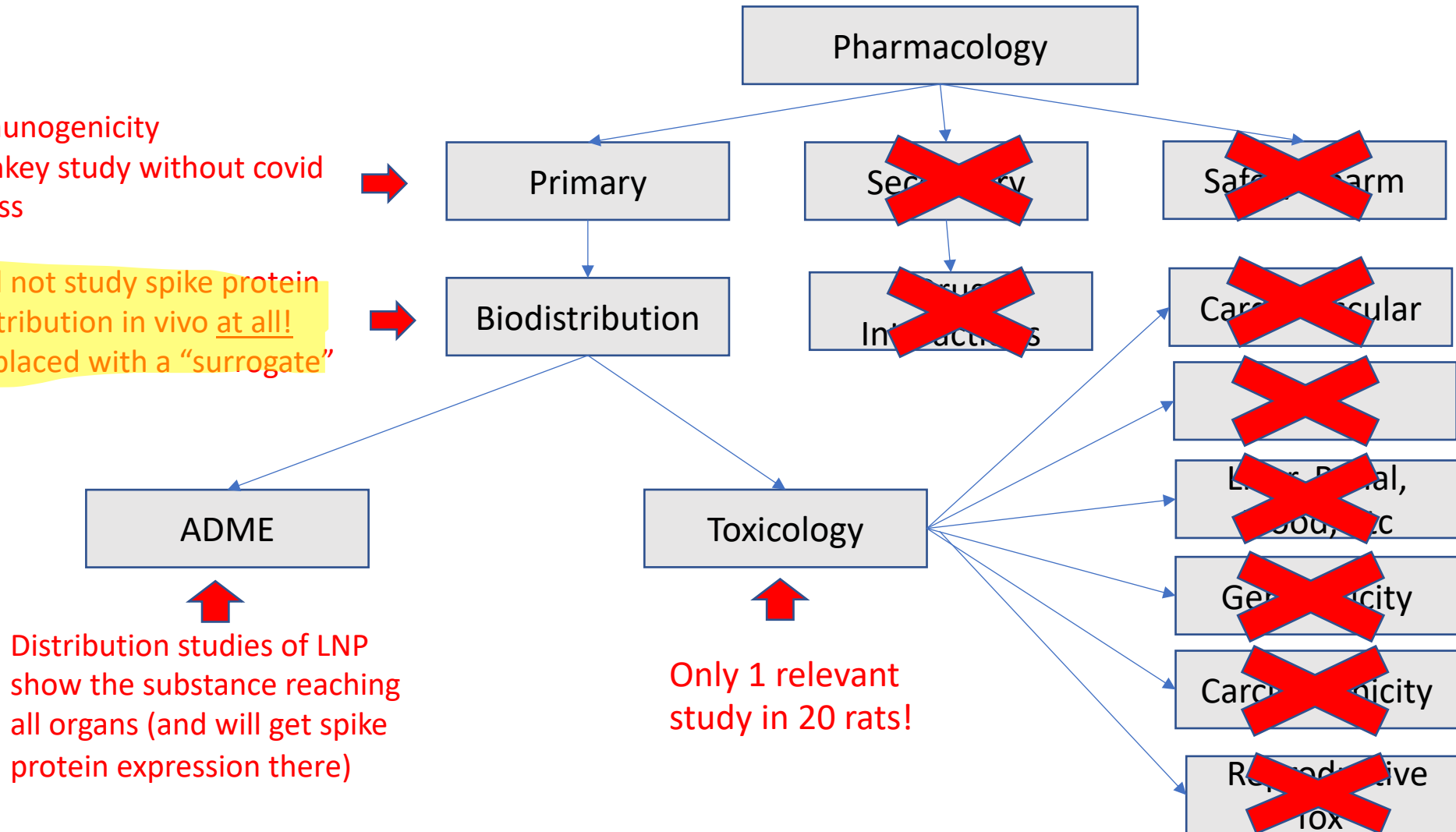
Table 7. AESIs Evaluation for BNT162b2

AESIs ^a Category	Post-Marketing Cases Evaluation ^b Total Number of Cases (N=42086)
Anaphylactic Reactions <i>Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria</i>	Please refer to the Risk 'Anaphylaxis' included above in Table 4.
Cardiovascular AESIs <i>Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia</i>	<ul style="list-style-type: none"> • Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed; • Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries; • Subjects' gender: female (1076), male (291) and unknown (36); • Subjects' age group (n = 1346): Adult^c (1078), Elderly^d (266) Child^e and Adolescent^f (1 each); • Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6); • Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours;



Summary of Pfizer's Non-Existing Non-Clinical Testing Program

- Immunogenicity
- Monkey study without covid illness
- Did not study spike protein distribution in vivo at all!
- Replaced with a "surrogate"



* Study not in compliance with Good Laboratory Practices, not acceptable for approval/labeling